Clinical Research on the Improvement of Balance Function of Patients with Knee Osteoarthritis by Electroacupuncture Combined with Exercise Therapy: study protocol for a randomized controlled trial

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Study protocol

Keywords: Knee osteoarthritis, Electroacupuncture, Pro-Kin254P balance test system

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Abstract

Background

Knee osteoarthritis (KOA) is a long-term, worsening knee disease that affects a lot of people in their middle years and later years. Its main symptoms are joint pain, limited movement, and a loss of proprioception. This makes it hard for older people to keep their balance, which makes them more likely to fall. This study looks at how well electroacupuncture and exercise therapy work together to treat early to mid-stage KOA. It also looks into how electroacupuncture and exercise therapy work together to improve balance in patients with KOA.

Methods

This protocol for a randomized, single-blind, controlled clinical study is proposed for this investigation. Sixty-six patients were to be admitted and randomly assigned to one of two groups: the treatment group (electroacupuncture plus exercise therapy) or the control group (exercise therapy). In the treatment group, electroacupuncture will be used in conjunction with exercise therapy: acupuncture was applied to the Dubi(ST35), Neixiyan (EX-LE4), Xuehai(SP10), Liangqiu(ST34), Yanglingquan(GB34), and Zusanli(ST36) for 20 minutes, followed by exercise therapy (muscle strength training and knee mobility training). The treatment schedule was identical for both groups: three times per week for four weeks, totaling 12 sessions. Before the first treatment session, after the first treatment session, after the 12th treatment session, and one month after the completion of treatment, static balancer function was measured, and VAS and WOMAC scales were recorded at the above 4 time points.

Discussion

The dynamic and static balance function test in the clinic is easy to perform, reliable, effective, and time-saving, which provides a basis for quantitative studies of clinical balance ability and can better complete the test that meets the aforementioned conditions and objectively evaluate the improvement of pain and functional impairment prior to and after treatment of KOA. It creates conditions for the establishment of a Chinese medicine rehabilitation treatment plan for KOA with certain efficacy and distinction.

Trial registration:

This trial has been approved by the Ethics Committee of the China Clinical Trials Registry, (approval number: ChiCTR2300071577). Date of Registration: 18 May 2023.

Introduction
Knee osteoarthritis (KOA) is a chronic, progressive knee disease that is prevalent among middle-aged and geriatric individuals\[1\]. Degeneration of the cartilage surfaces of the knee joint and secondary osteophytes are the most prominent alterations. With the development of an aging population in China, the high incidence and low cure rate of this disease have a significant negative impact on the mobility and quality of life of middle-aged and geriatric individuals. The most recent epidemiological data indicates that the incidence of KOA in China has reached 9.56\%\[2\]. In addition to damaging the bony joint, osteoarthritis of the knee impairs proprioception, resulting in a decrease in equilibrium and an increase in the risk of falls in elderly patients. Knee proprioception consists of afferent signals from receptors located in the muscles, tendons, joint capsule, ligaments, meniscus, articular cartilage, and skin surrounding the knee, which are processed in different centers and then sent out via reflex responses and muscle tone modulation circuits. Balance in the human body is dependent on the mutual participation and collaboration of the sensory and motor systems, which are under the control of the central nervous system, and abnormalities in any of these components can easily result in a loss of balance\[3\]. Balance deficits in KOA patients are exacerbated by decreased muscle strength in the lower extremities, decreased proprioception, and decreased joint range of motion \[4, 5\]. It has been demonstrated that the duration of disease, BMI, pain level, and daily functional mobility of KOA patients are related to indicators of dynamic and static balance, and that patients have a higher risk of falling due to their increased visual dependence on dynamic and static balance\[6\].

Pathological manifestations of KOA in contemporary medicine include progressive degeneration of the knee cartilage, ligaments, and joint capsule, as well as synovial inflammation of the knee joint and calcification of the subchondral bone\[7\]. Oral medication therapy (e.g., NSAIDs), intra-articular injections (e.g., sodium glacial), and surgical treatment (e.g., knee replacement) are typical modern medical treatment modalities\[8\]. Clinically, nonsteroidal anti-inflammatory drugs have been used extensively in recent decades due to their ability to provide rapid relief of osteoarthritis symptoms. However, these drugs do not help to stop the pathological progression of osteoarthritis, and the gastrointestinal side effects and cardiovascular accidents associated with long-term use are a concern for clinicians\[9\]. Current treatment aims to reduce pain, increase joint function, enhance quality of life, and slow disease progression. Therefore, there is an imperative need to discover a treatment that can effectively alleviate the symptoms of early to mid-stage KOA.

Rest and recuperation have traditionally been used to treat KOA in its early to middle stages. However, prolonged rest can cause deterioration and contracture of the bone, cartilage, ligaments, and surrounding muscles, resulting in a more severe functional decline and potentially severe negative effects on the stability of the lower limbs and lower spine\[10\]. Numerous domestic and international guidelines now recommend exercise therapy as the first-line treatment for KOA \[11\], including quadriceps muscle training, joint mobility training, aerobic exercise, and aquatic exercise therapy. Through active, long-cycle muscle exercises, the joint is periodically squeezed to maintain the normal metabolism of articular cartilage, improve cartilage nutrition, enhance the strength, thickness, and elasticity of articular cartilage, and inhibit the superficial rupture and inflammation of cartilage due to degeneration or degenerative changes\[12\]. This can significantly improve the maximum load in knee extension and the stability of the knee joint.
Due to the visualization and digitization of the type, waveform, and frequency of the electroacupuncture equipment in operation, electroacupuncture also has a significant application in scientific research. Modern electroacupuncture is extensively used in clinical and experimental research thanks to the efficiency of the mechanical age. Electroacupuncture is an additional method of di qi based on acupuncture. In Chinese medicine, the lancing of needles into various meridians of the body produces a stimulating effect in order to achieve therapeutic efficacy with a trace current close to the body's bioelectricity, which acts as a preventative and curative agent[13]. Several studies[14] have demonstrated that it increases local blood circulation, relieves contracture and tension in the muscles around the knee joint, and loosens adhesions in the muscles around the knee joint, thereby increasing the strength and endurance of the quadriceps muscle, the range of motion of the knee joint, and the function of the knee joint, so that satisfactory clinical results can be achieved.

For improving mechanical balance, however, there are few studies on acupuncture combined with exercise therapy for KOA. On the basis of previous research, an extensive literature evaluation was conducted, and the Pro-Kin254P balance test system[15] was used in conjunction with clinical research conditions that are currently implementable. The Pro-Kin254P balance test system is composed primarily of a pressure sensor, a computer, and software, with the pressure sensor measuring the balance plate's center of gravity.

Methods

Study design

This was a controlled, randomized, single-blind clinical trial. In Changning District, Shanghai, the Rehabilitation Department of Tianshan Hospital of Traditional Chinese Medicine recruited subjects. The patients will be divided into treatment and control groups using the random number table method, with the treatment group receiving electroacupuncture combined with exercise therapy and the control group receiving exercise therapy alone. The Ethics Committee of the China Clinical Trials Registry authorized the trial (approval number: ChiCTR2300071577). The trial's flowchart is depicted in Figure 1. Table 1 depicts the timeline for enrollment, interventions, and evaluation.

Patient recruitment

This research was to recruit 66 patients meeting the diagnostic criteria, all from Shanghai Changning Tianshan Traditional Chinese Medicine Hospital. The researcher initiated the introduction of this study, and the participants volunteered to take part. After screening by clinicians based on inclusion and exclusion criteria, subjects may be included if they satisfy the criteria, and all patients must provide written informed consent.

Inclusion criteria

(1) those who meet the Western diagnostic criteria and Chinese diagnostic criteria for KOA as described above; (2) those who are in the age range of 40 to 75 years; (3) those who agree and have signed the informed consent form; (4) those who have not used Western or Chinese medication and other therapies
related to the treatment of osteoarthritis of the knee within the last 1 month; (5) those with early to mid-
stage osteoarthritis of the knee, i.e., those who are graded for joint function (ACR criteria) or graded for
osteoarthritic radiological condition (Kellgren-Lawrence grading) grade II and grade III.

**Exclusion criteria**

(1) acute knee injury, osteoarthritic tuberculosis of the knee, tumour, rheumatic and rheumatoid
osteoarthritis, etc.; (2) significant narrowing of the joint space or formation of bony bridging joints or even
bony ankylosis on radiological imaging of the bone and joint; (3) significant knee deformity such as
inversion and valgus; (4) history of vascular nerve injury to the affected limb; (5) combined cardiovascular,
cerebrovascular, hepatic, renal, haematopoietic and other serious diseases; (6) psychiatric patients; (7)
pregnant and lactating women; (8) those who have received medication or other treatments related to
osteoarthritis of the knee within the last 1 month and have failed to terminate them.

**Rejection criteria**

(1) shedding: those who do not complete the full 12 sessions for various reasons; (2) contamination:
those who consume calcium-containing agents while undergoing treatment; (3) non-compliance: those
who do not follow the clinical trial regulations or do not follow the medical advice on their living
conditions, making it impossible to accurately determine the efficacy of the treatment; (4) those who
receive other treatments during the treatment period.

**Trial design**

Based on an estimate of the sample size, this study had at least 66 cases. Using SPSS 25.0 software and
a random grouping method, a large enough number of random numbers (more than 66) were made and
put in non-transparent boxes with sequential numbers. The numbered envelopes were given to the patients
in the order they entered the clinical study. The random numbers were then taken out of the envelopes and
put into the treatment group (electroacupuncture plus exercise therapy) and the control group (exercise
therapy only). For this procedure study, the person who collected the data, the intervention therapist, and
the person who analyzed the data were all blinded.

**Interventions**

**Treatment group (electroacupuncture plus exercise therapy):**

- **Electroacupuncture therapy procedures:**

  Dubi(ST35), Neixiyan (EX-LE4), Xuehai(SP10), Liangqiu(ST34), Yanglingquan(GB34), and Zusanli(ST36)
on the affected side. All acupoints were located according to the standard standards in the People's
Republic of China National Standard Acupoint Location GB13346-90[16]. Acupuncture Locations and are
exhibited in Table 2 and Figure 2. The patient is placed in a lying position, and the acupuncture points are
first disinfected locally and then referred to the operation method of "Acupuncture and Moxibustion,"
edited by Wang Hua, the editor-in-chief of the "Eleventh Five-Year Plan" national higher education textbook
of Chinese medicine[17]: use a No. 30 1 to 2 inch milli-needle, and pierce the body of the needle at 90° to the skin for 0.5 to 1.5 inches, respectively. Connect the G6805-2 electroacupuncture device, the calf nostril to the inner knee eye pair, and the blood sea to the Liangqiu pair after obtaining qi. The stimulation parameters are direct current, continuous wave, 2 Hz frequency, 0.5 ms wave width, and current intensity, which is the utmost intensity the patient can tolerate 20 minutes after the needle has been energized. Three times per week for four weeks, a total of 12 sessions were administered.

- Exercise therapy[18-20]:

When exercise therapy is being used, the main focus is on building muscle power and improving joint mobility. Three times a week for about 20 minutes each (two sets of 10 reps each) for 4 weeks, or 12 workouts in total. Here is a list of what needs to be done:

(A) Building muscle strength: Strength training for the quadriceps and the vastus medialis muscle

a. Training the quadriceps

1) Isometric training of the quadriceps. This means that when the muscle is tightened, there is no movement of the joint. The exercise is split into two groups: those that raise the leg straight up and those that tighten the leg muscles. Straight leg raise exercise: Have the patient lie on his back, straighten the knee joint, raise the affected limb at an angle of about 30° to the bed, and raise the toe dorsiflexion position about 30–40 cm. The quadriceps muscle then contracts hard and holds this position for more than 5 seconds, then lets the knee joint rest for 5 seconds, and then repeats the exercise. Leg-tensing exercise: Straighten the knee joint, move the ankle joint dorsally, and tighten the quads so that the patella can't be moved. Hold for more than 5 seconds until you feel your muscles getting sore, then let go for a second and do it again. Weighted straight leg raise: This is the same movement as the straight leg raise, but with a weight on the raised leg at the ankle. The weight starts at 1kg and goes up to 3kg over time.

2) Isotonic training of the quadriceps: the tone of the muscles stays the same and joint movements are made. When the person is sitting in a chair, the injured knee is quickly straightened and the foot is bent backward. When the knee has been kept for more than 5 seconds, the muscles are relaxed and the knee is slowly moved away. Repeat the exercise, doing it twice a day for about 10 minutes each time until your thighs hurt. Long circle exercise with weights Sit the patient on the edge of the bed, bend the knee 90 degrees, lower the calf, start with a 5 kg weight on the back of the foot and gradually increase it to 10 kg, lift and straighten with the weight.

b. Training the vastus medialis muscle

In the supine position, put a soft pillow behind the patient's knee and tell him or her to bend the knee 20 degrees and straighten it the last 10 degrees, keeping the knee under the most pressure on the pillow until the knee is mostly sore. Each extension should last 5 seconds and there should be two sets of five exercises per day. For the weighted short arc exercise, the patient sits on the bed and a soft pillow is put
under the affected knee to bend it 30°. This is followed by a weighted exercise of the affected limb, starting at 3kg and gradually rising to 5kg for leg raising and extension.

(B) Knee movement training: exercises that bend and straighten the knee

1) The knee bends forward It is enough to bend the knee until pain is felt in the front of the patella.

2) Extension training: lying on your back with your knees as straight as you can get them. Place the knee joint between the distal and proximal patella and press back on the knee joint until you feel pain behind the knee. This is hip abduction in the lateral position and knee adduction in the flat position.

Control group (Exercise therapy only):

This group did the same kinds of exercises as the treatment group. Over the course of four weeks, treatment was given three times a week, for a total of 12 lessons.

Outcomes

Primary outcome

WOMAC scale score[21, 22]: Checking on the state before the first treatment, after the first treatment, after the 12th treatment, and one month after treatment is done. The WOMAC scale was used to measure how well the joints were working. The scale has three parts: joint pain, joint stiffness, and trouble moving. These are the most common signs and symptoms of osteoarthritis in the whole knee. The pain section has five items that add up to 20 points, the stiffness section has two items that add up to 8 points, and the trouble moving around section has 17 items that add up to 68 points. Together, the three sections, which have 24 items, add up to 96 points. A special system is used to give points. The patient stands on the other side of the scale and moves it upstream until it is in the right place to show the application. The researcher looks at the scale on the front to figure out how bad the knee pain is. A score of 0 means there is no pain, a higher score means the pain is worse, and a score of 10 means the pain is the worst or even unbearable. The total score is the sum of all 24 VAS scores. A higher total score for each of the 24 items in the 3 sections means that the situation is worse. The WOMAC scale is a thorough and detailed way to measure how well a joint works in people with osteoarthritis of the knee. It gives a clear, accurate, and sensitive picture of how well the knee works before and after treatment.

Secondary outcomes

Determination of dynamic and static apparatus equilibrium function[15, 23, 24]: A balance feedback trainer (Tecnobody, Italy; Pro-Kin254P balance test instrument) is utilized. This instrument accurately measures the patient's equilibrium function. Before the first treatment, after the first treatment, after the 12th treatment, and one month after treatment completion, the instrument is measured. The static and dynamic balance assessment module is selected to conduct a static stability test in the standing position, and the four locking blocks that come with the system are positioned and secured beneath the balance board. Patients stand barefoot on the balance board and symmetrically in the center of the force
measuring table, with their second toes facing the A2 and A8 lines of the balance board, their heels together on the A1 and A5 lines, and the highest point of their bilateral arches on the A3 and A7 axes. The upper extremities hang naturally on both sides of the body, while the chest is raised and the head is directed forward. The patient should make every effort to maintain an upright and stable position, with eyes open and closed three times each. Indicators include the mean center of pressure along the x-axis (C.O.P(x)), the mean center of pressure along the y-axis (C.O.P(y)), the standard deviation along the anterior-posterior axis (SDofap), the standard deviation along the lateral axis (SDofla), the mean speed of movement along the anterior-posterior axis (ASofap), the mean speed of movement along the lateral

**VAS score[25]:** monitor the condition at four time points: before the first treatment, after the first treatment, after the 12th treatment, and one month after treatment has concluded. Using a visual analogue scale (VAS), the reduction in discomfort is measured. As described above, a unique scoring scale was used. The patient confronts the reverse side of the scoring ruler and independently moves the ruler upstream to the position corresponding to pain. The researcher evaluates knee pain using the scale on the front: a score of 0 indicates no pain, a score of 1 indicates moderate pain, and a score of 10 indicates severe or even intolerable pain. The VAS scores are recorded in centimeters to the nearest millimeter, with one decimal place.

**Five Times Sit-to-Stand Test (FTSST)[26, 27]:** The 5-Times Sit-to-Stand Test is used to check how well older people's leg muscles are working, especially when they are sick or getting older. The sit-to-stand test is used to measure the lower limb strength, balance, and movement of older people[28, 29]. It is a very good way to predict how likely an older person is to fall. It can be used as a test of knee function and requires the participant to stand up as quickly as possible from a chair with a height of 46 cm and no armrests, with their hands crossed over their shoulders and without using their arms for support. They must do this five times in a row. If this isn't possible, the chance of falling needs to be looked at again.

**SF-36[22, 30]:** The SF-36 has been used a lot to measure people's quality of life, figure out how well clinical studies work, and make decisions about public health. The SF-36 is a simple health survey that measures the following effects of health on society: The Physical Functioning subscale measures the functional limitations caused by physical health problems. The Bodily Pain subscale measures the impact on daily life. The General Health subscale measures the individual's assessment of his or her health status and trends. The Vitality measures the individual's subjective feelings about his or her energy and fatigue. The Social Functioning subscale measures how physical and mental health problems affect the ability to interact with others. The Mental Health subscale measures four types of mental health: motivation, depression, behavioral or emotional problems, and psychological health. The interviewees’ quality of life is looked at from eight different points of view, such as motivation, depression, behavioral or emotional control, and subjective feelings[31].

**Adverse events**

Incidence of adverse reactions: Clinical observation for possible signs of adverse reactions like dizziness, treatment site infection, and swelling, as well as systemic adverse reactions; observation for other
unexpected adverse events and serious adverse events that happen. Based on the situation, the investigator decides if the person needs to see a doctor or get treatment, and if the observation should end. If a major side effect happens, the unit running the clinical study must treat the subject right away to make sure they are safe. The detective fills out the Serious Adverse Event Report Form, tells the Ethics Committee about it within 24 hours, signs and dates the report, and sends it to the committee.

**Assessment of safety**

Adverse events were found by asking the patient questions (being careful not to ask leading questions), measuring the patient’s kinetic and static balance before and after treatment, using the Womac scale, the VAS score, doing a physical check, and figuring out what caused the adverse events.

**Data collection, management and monitoring**

All information about clinical trials is kept in good shape and handled by a dedicated person. The inspector fills out the case report form (CRF) honestly and doesn’t change it as much as possible. If a mistake is made, it shouldn’t be crossed out; instead, a line should be drawn through it, and the professional observer should sign next to it and write the date and reason. Adverse events were found by asking the patient questions (being careful not to ask leading questions), measuring the patient’s kinetic and static balance before and after treatment, using the Womac scale, the VAS score, and a physical check, as well as figuring out why adverse events happened.

**Sample size**

The content of the sample was figured out using a randomized, controlled, two-sample rate comparison sample content estimation method in a clinical design based on previous studies and a lot of research. The method was worked out by looking at Medical Statistics, 2nd Edition, which came out in August 2007 from China Union Medical University Press[32]. Taking into account a shedding rate of no more than 10%, the sample rate difference was found to be 10%. The sample size needed was 66 cases, which were split evenly between the treatment group and the control group, with 33 cases in each group. Taking $\alpha = 0.05$ and $1-\beta = 0.8$, the following equations were used to figure out the sample size:

$$n_2 = \frac{(z_\alpha + z_\beta)^2}{(\varepsilon - \delta)^2} \left[ \frac{p_1(1 - p_1)}{\kappa} + p_2(1 - p_2) \right]$$

**Quality Control**

In this project, the study principal and the participating investigators all unified the standard operating procedures before starting the study.
The project leader and the clinical study supervisor will also train all investigators on the trial protocol so that they can understand and be familiar with the trial process, intervention protocol, clinical efficacy assessment and contingency planning for adverse events. The implementation of quality control and quality assurance systems for clinical trials should also be ensured. All observations and findings in clinical trials should be verified to ensure the reliability of the data and the traceability of the original data. Regular trial hospital site monitoring visits should be conducted to ensure proper implementation of the study protocol. During project execution, clinical interventionists, laboratory examiners and statisticians are set up blinded to ensure independent analysis to avoid data bias.

**Statistical analysis**

Standard operating procedures (SOP) for managing data from clinical studies were followed. SPSS 25.0 statistical analysis software was used to look at all of the collected data. First, the measurement values were checked to see if they were normal. Those that were normal were written as s. ANOVA was used to compare measurements before and after treatment within the same group. An independent samples t-test was used to compare measurements between groups at the same time point. A rank sum test was used for measurements that were not evenly spread out. The 2-test, which is a non-parametric test, was used to test information in the count data that was not ranked, while the Ridit test was used to test information that was ranked. (α= 0.05 test level, so a difference with P value of 0.05 is statistically significant.) During the process of analyzing data, statisticians did not work with the people who designed and ran the project study.

**Discussion**

Researchers at home and abroad who have studied balance have found that the ability to control one's posture is closely linked to the ability to control oneself. Several clinical studies[33–35] have shown that using exercise therapy to treat patients with osteoarthritis of the knee can effectively relieve pain, prevent muscle atrophy, improve muscle strength in the affected limb, improve joint mobility, improve balance, and overall improve somatic function and quality of life, as well as delay the time when patients need surgery. Exercise therapy training before and after surgery can also shorten a person's time in the hospital and cut down on the cost of medical care[36]. It works better to stop people from falling when they are older. In this project, we'll use the parts of exercise treatment that involve building muscle and moving joints.

Based on this trait, static and dynamic balance posture maps can also be used to test how stable a person's posture is. Static and dynamic balance posture charts are used for quantitative studies of clinical balance because they are easy to use, reliable, true, and save time. It is also possible to measure how much balance is lost and how much it is made up for over time. The quantitative factors are the length of the path, the area of the path, the speed of the oscillation, the frequency of the oscillation, the pendulum's amplitude, and the ratio of the longitudinal to transverse pendulum[15, 23, 24]. The ratio of longitudinal to transverse amplitude is one of the best ways to spot problems with posture and lack of balance.
The pulsed electrical stimulation caused by the electroacupuncture device controls the function of the body’s neurohumoral system, which is controlled by the body’s neurohumoral system. This helps to reduce pain and swelling and calm and relax the body[14]. So, when electroacupuncture is used to treat KOA, the major effects are anti-inflammatory, pain relief, and a reduction in swelling. Exercise therapy, on the other hand, is likely to improve the motor function of the limb through active and passive exercise, training to build muscle power, and training to move the knee joint. So, if you have osteoarthritis of the knee, you can expect that combining electroacupuncture and exercise therapy will have a better rehabilitation benefit in terms of reducing inflammation and pain and improving limb function.

Some studies have also shown that electroacupuncture can help people with pain and stiffness in their joints feel better. Some studies[15] have found that the muscle vibration caused by electroacupuncture treatment has a good passive contraction effect on the quadriceps muscle, which speeds up local blood circulation, relieves the contracture and tension of the muscles around the knee joint, and loosens the adhesions of the muscles around the knee joint. This increases the strength and endurance of the quadriceps muscle, the range of motion of the knee joint, and the function of the knee joint.

Based on the research[33, 37], the most common acupuncture spots for treating KOA are Dubi, Neixiyan, Xuhai, Yanglingquan, Zusanli and Liangqiu. In this study, the acupuncture points chosen are the same points chosen above. Most of the important acupuncture points are around the knee joint, which is in line with the idea that acupuncture should be done near the problem. Liang Qiu can be used to treat knee pain caused by bending and straightening the knee. Dubi also called the “Waixiyan” is used to treat knee pain. When the knee is bent, acupuncture at this point can enter the joint cavity. The surface of the articular cartilage of the knee has nerve distribution, which is also a cause of painful knee injuries, and acupuncture directly stimulates some of the nerves to get analgesic effects. Some studies have shown that deep acupuncture at the Dubi point and Neixiyan point can help ease pain and improve joint function. For systemic tonicity, the Zusanli point is an important point. When acupuncture is done at this point, it has the effect of controlling the body’s immune system, making it more resistant to disease, strengthening the middle and helping the qi, opening the channels and turning them on, getting rid of wind and dampness, and helping to get rid of bad things. Most people with KOA have pain in the middle of the knee, especially around the Neixiyan point. This pain can be treated with acupuncture at the Neixiyan point. The Xuehai point works to get the blood moving again. Over time, knee pain will cause blood to pool in the area, and Xuehai can get the blood moving again to help the joints around it work better.

In conclusion, this topic selects acupuncture points near to the knee joint lesion in order to treat both the symptoms and the underlying cause of the disease. The tendon capital, Yanglingquan, can treat knee and foot disorders. Zusanli and Liangqiu which are used to strengthen Qi and nourish Blood, respectively. The combined use of these acupuncture points can assist in clearing the meridians and channels, revitalizing the circulation, and alleviating pain.

The study was conducted at a single center with a still-small sample size, so this topic still has some limitations. This study, however, meets the methodological requirements of a randomized, single-blind, controlled trial with an outcome assessor and statistician. In addition, cartilage injury typically occurs
during activity in patients with KOA, along with pain and functional impairment. The dynamic and static balance function test in the clinic is easy to perform, reliable, effective, and time-saving, which provides a basis for quantitative studies of clinical balance ability and can better complete the test that meets the aforementioned conditions and objectively evaluate the improvement of pain and functional impairment prior to and after treatment of KOA. It creates conditions for the establishment of a Chinese medicine rehabilitation treatment plan for KOA with certain efficacy and distinction.

**Trial Status**

This trial has been approved by the Ethics Committee of the China Clinical Trials Registry, (approval number: ChiCTR2300071577). Date of Registration: 18 June 2023. The recruitment of participants has started on 6 June 2023 and is still ongoing. The estimated completion date of recruitment is 31 May 2026 as a result of multiple movement restriction orders in China due to the COVID-19 pandemic.

**Abbreviations**

KOA= knee osteoarthritis, FTSST=five times sit-to-stand test, VAS=visual analogue scale, SOP= standard operating procedures, CRF= case report form

**Declarations**

**Authors’ contributions**

Kun Xue and Wang Lu contributed to the conception of the study. The manuscript protocol was drafted by Kun Xue, and was revised by Ji Wu, Wang Lu and Minghui Hang. Jie Bao and Yun Zhao developed the search strategies, and will implement them. Yusun Lu, Qiong Xu and Chunshui Huang will extract data of included studies, assess the risk of bias and complete the data synthesis. All authors approved the publication of the protocol.

**Funding**

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**Ethics approval and consent to participate**

The trial has received ethics approval from the Ethics Committee of Shanghai Changning Tianshan Hospital of Traditional Chinese Medicine (approval number: 2020TSKY05). This trial has been approved by the Ethics Committee of the China Clinical Trials Registry, (approval number: ChiCTR2300071577). Date of
Registration: 18 May 2023. All patients we recruited will provide written informed consent before participation. The study protocol conforms to the principles of the Declaration of Helsinki.

Consent for publication

All the authors gave their consent to publish the paper.

Availability of data and material

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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References


Tables
Table 1
The schedule of enrollment, interventions and assessments are presented.

<table>
<thead>
<tr>
<th>Study Period</th>
<th>Screening</th>
<th>Baseline</th>
<th>Follow-up assessment time</th>
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<td>Timepoint</td>
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<td>After the 12th treatment(4wk)</td>
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<td>1 month after completion of treatment(8wk)</td>
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**Enrolment:**

- Eligibility screen
- Informed consent
- Allocation

**Interventions:**

- Experimental group
- Control group

**Assessments:**

- Physical examination
- Acupuncture Safety and tolerance test
- Blind method success rate test
- WOMAC
- Pro-Kin254P Balance Test System
- VAS
- 5 Times Sit-to-stand Test
- SF-36
Table 2
Locations and manipulations of acupoints.

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<thead>
<tr>
<th>Acupoint</th>
<th>Location</th>
<th>Manipulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xuehai (SP10)</td>
<td>Flex the knee, 2 inches above the medial superior border of the patella, when the bulge of the medial head of the quadriceps muscle is present</td>
<td>Puncture perpendicularly to a depth of 1–1.5 cun</td>
</tr>
<tr>
<td>Liangqiu (ST34)</td>
<td>Flex the knee, on the line between the anterior superior iliac spine and the external superior border of the patella, 2 inches above the external superior border of the patella</td>
<td>Puncture perpendicularly to a depth of 1–1.5 cun</td>
</tr>
<tr>
<td>Dubi (ST35)</td>
<td>Flex the knee at the lateral recess of the patellar ligament</td>
<td>Oblique puncture to the outside of the knee 0.5-1 cun</td>
</tr>
<tr>
<td>Zusanzli (ST36)</td>
<td>Three cun directly below Dubi, and 1 finger-breadth lateral to the anterior border of the tibia</td>
<td>Puncture perpendicularly to a depth of 1–2 cun</td>
</tr>
<tr>
<td>Yanglingquan (GB33)</td>
<td>In the anterior inferior depression of the fibular tuberosity</td>
<td>Puncture perpendicularly to a depth of 1–1.5 cun</td>
</tr>
<tr>
<td>Neixiyan (Ex-LE04)</td>
<td>Flex the knee at the medial recess of the patellar ligament</td>
<td>Oblique puncture to the inside of the knee 0.5-1 cun</td>
</tr>
</tbody>
</table>

Figures
Figure 1
Flow diagram
Figure 2

Locations of acupoints

Supplementary Files

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

- KunXueSPIRITChecklist.pdf