

# The efficacy of jade moxibustion in knee osteoarthritis

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<b>Registration date</b> 28/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/06/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Osteoarthritis, a common joint disorder, is the most common form of arthritis in the world. The knee joint is the most common site affected by osteoarthritis. Joint pain caused by knee osteoarthritis can severely reduce the patient's quality of life. The aim of this study is to compare the effects of jade moxibustion and traditional moxibustion on knee pain in osteoarthritis.

### Who can participate?

Patients aged 50 to 75 undergoing conventional knee osteoarthritis treatment

### What does the study involve?

Participants are randomly allocated to be treated with either jade moxibustion or traditional moxibustion at the acupoints on the affected knee(s). Patients in both groups receive 20 minutes of treatment, three times per week for 4 weeks. The effects of treatment are assessed through questionnaires at the start of the study and at 2, 4, 8, 12 and 24 weeks after they join the study. The assessments will take place at either Tongren Hospital or Shanghai Pudong Hospital except for the assessment at 24 weeks, where the questionnaire will be mailed to participants.

### What are the possible benefits and risks of participating?

Jade moxibustion and traditional moxibustion can reduce pain and improve knee joint stiffness and function in patients with knee osteoarthritis. Some patients might have local skin flushing or blistering (not instantly, but usually one day after treatment) at the site of treatment. Usually, the blister is naturally absorbed within a day or two without obvious scarring of the skin.

### Where is the study run from?

1. Tongren Hospital Affiliated to Shanghai Jiaotong University (China)
2. Shanghai Pudong Hospital of Traditional Chinese Medicine (China)

### When is the study starting and how long is it expected to run for?

May 2019 to June 2021

Who is funding the study?  
Shanghai Key Laboratory of acupuncture mechanism and acupoint function (China)

Who is the main contact?  
Prof. Xueyong Shen  
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## Contact information

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Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

## Study information

**Scientific Title**

Comparison of the efficacy of jade moxibustion and traditional moxibustion in knee osteoarthritis: a pilot randomized clinical trial

**Study objectives**

A 4-week jade moxibustion treatment regimen will reduce pain among patients with knee osteoarthritis as compared with traditional moxibustion treatment, and the therapeutic effect might be related to the cytokines such as Interleukin in serum.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 10/07/2019, Institutional Review Board (IRB) of Tongren Hospital Affiliated to Shanghai Jiaotong University (Room 309, Building 6-3, 1111 Xianxia Road, Changning District, Shanghai, China, 201103; +86 (021) 52039999-96341), ref: 2019-022-02

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Knee osteoarthritis

**Interventions**

Patients with knee osteoarthritis are randomly allocated into either jade moxibustion or traditional moxibustion groups.

Patients will receive jade moxibustion or traditional moxibustion treatment on ST35, ST34, EX-LE4, SP10 and Ashi points in the area of the affected knee(s). Patients in both groups receive 20 minutes of treatment, 3 times per week for 4 weeks.

The effects of treatment on the most painful joint (which is identified through participant report at baseline and is the joint assessed throughout the study) are assessed at the hospital at baseline, 2 (mid-term), 4 (the end of treatment), 8, and 12 weeks after baseline. During the follow-up period (5 to 24 weeks), the subject report on adverse events and side effects will be sought via telephone call weekly. At 24 weeks, the questionnaire will be mailed to the subjects and they will be asked to post them back after filling them out.

Participants will be allowed to take any analgesic or non-steroidal anti-inflammatory drugs that they used before the study. They will be asked to record the daily dose during the entire clinical trial, and then the investigators will analyze the changes in the dose.

### **Intervention Type**

Other

### **Primary outcome(s)**

Knee pain, measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score at baseline and 2, 4, 8, 12, and 24 weeks

### **Key secondary outcome(s)**

1. Knee function measured using the WOMAC function score at baseline, weeks 2, 4, 8, 12, and 24 weeks
2. Knee stiffness measured using the WOMAC stiffness score at baseline, weeks 2, 4, 8, 12, and 24 weeks
3. Knee osteoarthritis symptoms measured using the WOMAC total score at baseline, weeks 2, 4, 8, 12, and 24 weeks
4. Knee pain measured using the Visual Analogue Scale (VAS) pain score at baseline, weeks 2, 4, 8, 12, and 24 weeks
5. Sensation measured by investigator question "What do you feel during the treatment?" (with possible answers of: heat, cold, pain, no feeling, or other which will be described)
6. Quality of life measured using the 36-Item Short Form Health Survey (SF-36) at 4, 12 and 24 weeks and the Quality of Life Scale (QOLS) at 4 weeks
7. Participant perception of the safety of the treatment measured by investigator question (with possible answers of: safe, less safe, safety problem, or serious safety problem) at 4 weeks
8. Dose of analgesic or non-steroidal anti-inflammatory drugs consumed, determined through daily participant reports from baseline to 24 weeks
9. Any adverse events or side effects during the study are determined from the subject and investigator reports collected weekly from baseline to 24 weeks. Common side effects include redness and blisters by jade moxibustion and traditional moxibustion. Serious adverse events will also be reported to the Ethics Committee

### **Completion date**

30/06/2021

## **Eligibility**

### **Key inclusion criteria**

1. Aged 50 to 75 years
2. Knee osteoarthritis according to the American College of Rheumatology Diagnostic Criteria
3. Radiologic confirmation of knee osteoarthritis (Kallgren-Lawrence level  $\geq 1$ )
4. Moderate to severe knee pain on most days of the past month (VAS score for arthritic pain  $\geq 40$ )
5. Has a full understanding and gives informed consent to participate in the study

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

94

**Key exclusion criteria**

1. Knee pain caused by other diseases (such as rheumatoid arthritis, fibromyalgia syndrome, chronic fatigue syndrome, and ankylosing spondylitis)
2. Treatment with steroid drugs in the past 3 months
3. Received acupuncture or moxibustion treatment in the past 3 months
4. Intra-articular injection of hyaluronate in the past 6 months
5. Joint puncture or arthroscopy in the past year
6. Previous (or planned for during the trial) knee or hip replacement surgery
7. Use of other topical treatments for osteoarthritis of the knee
8. Diagnosis of any serious diseases including, but not limited to, heart disease, lung disease, kidney disease, liver disease, malignant tumor, systemic infection, infectious disease, and/or mental illness
9. Participation in another clinical study in the past month

**Date of first enrolment**

10/07/2019

**Date of final enrolment**

31/12/2020

**Locations**

**Countries of recruitment**

China

**Study participating centre**

**Tongren Hospital Affiliated to Shanghai Jiaotong University**

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## Sponsor information

### Organisation

Shanghai University of Traditional Chinese Medicine

### ROR

<https://ror.org/00z27jk27>

## Funder(s)

### Funder type

Industry

### Funder Name

Shanghai Key Laboratory of Acupuncture Mechanism and Acupoint Function

### Alternative Name(s)

SKLAA

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Research institutes and centers

### Location

China

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Xueyong Shen (sxy1@shutcm.edu.cn) or Dr Lusheng Chen (13681913509@163.com).

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		04/06/2023	05/06/2024	Yes	No
<a href="#">Protocol article</a>	protocol	01/04/2020	27/04/2020	Yes	No