

# The effect of infrared heating or traditional moxibustion in osteoarthritis of the knee

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 05/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/07/2021	<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. Based on previous research, traditional moxibustion and laser moxibustion could relieve pain effectively and improve function in patients.

Moxibustion is a type of traditional Chinese medicine. It involves burning moxa, a cone or stick made of ground mugwort leaves, on or near your body's meridians and acupuncture points. The aim of this study is to compare the effects of laser 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 CO2 laser 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?

CO2 laser 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?

June 2019 to May 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

### Type(s)

Public

### Contact name

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### Contact details

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## Additional identifiers

## Study information

### Scientific Title

The efficacy of moxibustion and infrared laser moxibustion in knee osteoarthritis: A randomized non-inferiority study

### Acronym

EILMK

### Study objectives

A 4-week CO2 infrared laser moxibustion will reduce pain and improve knee joint stiffness and function among patients with knee osteoarthritis as compared with traditional moxibustion treatment

### 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; no email provided), ref: 2019-022-02

## **Study design**

Interventional 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 CO2 laser moxibustion or traditional moxibustion groups.

Patients will receive CO2 laser moxibustion or traditional moxibustion treatment on ST35, EX-LE4 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.

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.

Laser moxibustion: The wavelength of laser irradiation was 10.6  $\mu\text{m}$ , and the output power was adjusted in the range of 160-180 mW. Energy density ranged from 61.2 to 68.8 J/cm<sup>2</sup> for one treatment.

Traditional moxibustion We used a commercially available moxibustion device (Nanyang Hanyi Moxa Company, Ltd., Nanyang, Henan, China). It has a cylindrical opening to hold a pillar of moxa; at its base is an adhesive membrane. During treatment, the device is placed at an acupoint, and the moxa is burned about 8 mm above the skin.

Both groups have 20 minutes of treatment.

## **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. The 50-yard walking time was assessed and recorded among the participants at baseline, weeks 4 and 12 weeks to observe improvements in walking.
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

### **Completion date**

01/05/2021

## **Eligibility**

### **Key inclusion criteria**

Patients aged 50 to 75 undergoing conventional knee osteoarthritis treatment

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Other

### **Sex**

All

### **Total final enrolment**

92

### **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**

15/07/2019

**Date of final enrolment**

01/01/2021

## Locations

**Countries of recruitment**

China

**Study participating centre**

**Tongren Hospital Affiliated to Shanghai Jiaotong University**

No.1111 Xianxia Road Changning District

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**Study participating centre**

**Shanghai Pudong Hospital of Traditional Chinese Medicine**

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201200

## Sponsor information

**Organisation**

Shanghai University of Traditional Chinese Medicine

**ROR**

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

## Funder(s)

**Funder type**

University/education

**Funder Name**

Shanghai University of Traditional Chinese Medicine

**Alternative Name(s)**

Shanghai University of TCM, SHUTCM

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

China

## Results and Publications

**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/07/2021	16/07/2021	Yes	No