

# Effects of moxibustion on patients with knee osteoarthritis

<b>Submission date</b> 03/04/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<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 patients quality of life. The purpose of this study is to observe whether the traditional Chinese medicinal therapy moxibustion provides greater relief from pain and joint stiffness and improved function.

### Who can participate?

Patients aged 45 years or older, male or female, undergoing conventional knee osteoarthritis treatment.

### What does the study involve?

Patients were randomly allocated to receive either real or sham moxibustion. Patients in both groups received 20 minutes of treatment, three times per week for 6 weeks. The effects of treatment were assessed at the start of the study and after 3 weeks, 6 weeks (the end of treatment), 12 weeks and 24 weeks.

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

Moxibustion can reduce pain and improve knee joint stiffness and function in patients with knee osteoarthritis. Some patients have had local skin flushing or blistering (not instantly, but usually 1 day after treatment) at the site of treatment. Usually the blister was naturally absorbed within 3 days without obvious scarring on the skin.

### Where is the study run from?

Traditional Chinese Medicine Hospital of Pudong New District, Shanghai, China; the Community Service Center of Chuansha, Pudong, Shanghai, China; and the Nantong University's affiliated hospital, Nantong, China.

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

The study started in August 2009 and recruitment ended in November 2011.

Who is funding the study?

National Basic Research Program of China, National Natural Science Foundation of China, The Key Program of State Administration of Traditional Chinese Medicine of China, and the Shanghai Municipal Science Foundation.

Who is the main contact?

Prof. Xueyong Shen  
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## Contact information

### Type(s)

Scientific

### Contact name

Prof Xueyong Shen

### Contact details

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## Additional identifiers

### Protocol serial number

ChiCTR-TRC-11001408

## Study information

### Scientific Title

Effectiveness of moxibustion treatment as adjunctive therapy in osteoarthritis of the knee: a randomized, double-blinded, placebo-controlled clinical trial

### Study objectives

The hypothesis is that the moxibustion can reduce pain and improve knee joint stiffness, function, and quality of life in patients with knee osteoarthritis.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Institutional Ethic Review Committee of Chinese Clinical Trials Registry, 28/06/2011, ChiECRCT-20110022

### Study design

Multi-centre double-blind randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Knee osteoarthritis

## **Interventions**

Patients with knee osteoarthritis were randomly divided into real and sham moxibustion groups. Patients received moxibustion and sham moxibustion treatment on Dubi (ST-35), EX-LE4, and an Ashi point in the area of the affected knee(s). Three consecutive moxa pillars were burned at each point. Once the device was affixed at a point, the first pillar was lit. After burning, the residual pillar was removed and another pillar was inserted and burned. A pillar burns for about 6 min, making the moxibustion session about 20 min long. Patients in both groups received 20 minutes of treatment, three times per week for 6 weeks.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

WOMAC (VAS3.1) Questionnaire was applied to assess the therapeutic effects in terms of joint pain, stiffness, and functional disorder of the participants at 3 weeks and 6 weeks after the treatment initiation, and the long-term effects were also assessed at 12, and 24 weeks after baseline

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

1. Short Form 36 (SF-36) component scales were used to assess health-related quality of life at baseline, week 3, week 6 and week 12
2. The 50-yard walking time was assessed and recorded at baseline and week 6 to observe the improvement in walking

## **Completion date**

30/04/2012

## **Eligibility**

### **Key inclusion criteria**

1. Male or female, 45 or older, with knee osteoarthritis diagnosed according to American College of Rheumatology criteria, including radiographic evidence of at least one osteophyte at the tibiofemoral joint in one or both knees (KellgrenLawrence score 2 or 3)
2. Pain score of at least 3 points on a 10-point visual analogue scale for most days during the

previous month

3. Willingness to sign the consent form and be randomly assigned into either a treatment or a placebo group

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Key exclusion criteria**

1. Presence of serious medical conditions that preclude participation in the study
2. Intra-articular corticosteroid or hyaluronate injections, knee surgery, or use of topical capsaicin cream during the preceding 6 months
3. Previous experience with moxibustion
4. Planned events such as knee replacement that would interfere with participation in all 24 weeks of the study

**Date of first enrolment**

01/08/2009

**Date of final enrolment**

01/11/2011

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

1200 Cailun Road

Shanghai

China

201023

## **Sponsor information**

**Organisation**

Shanghai University of Traditional Chinese Medicine (China)

**ROR**

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

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Basic Research Program of China (2009CB522901)

### **Funder Name**

National Natural Science Foundation of China (81320108028, 81202648)

### **Alternative Name(s)**

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

China

### **Funder Name**

The Key Program of State Administration of Traditional Chinese Medicine of China (ZYSNXD-CC-ZDXK-07)

### **Funder Name**

The Shanghai Municipal Science Foundation

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	24/06/2014		Yes	No
<a href="#">Results article</a>	results	01/06/2015		Yes	No
<a href="#">Results article</a>	results	01/06/2020	17/12/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes