

Traditional Chinese acupuncture for mild to moderate knee osteoarthritis

Submission date 04/04/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 04/07/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/08/2023	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is the most common type of arthritis and affects millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. The knee is the most common joint to be affected by OA and in many sufferers, the pain prevents people from moving around leading to muscle weakness and disability. Acupuncture is a popular treatment taken from ancient Chinese medicine, in which fine needles are placed into the body at specific points. Studies have shown that it can help to stimulate nerves under the skin, causing the body to produce natural pain-relieving substances (endorphins). The aim of this study is to evaluate the effectiveness of acupuncture in reducing pain and improving function in patients with knee OA.

Who can participate?

Patients diagnosed with mild-moderate knee osteoarthritis.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive traditional Chinese acupuncture, which involves having needles placed in acupoints (locations on the body affected by acupuncture) which are stimulated manually for 10 seconds to create the intended sensation. Those in the second group receive minimal acupuncture, which involves having needles placed under the skin at non-acupoints very shallowly so that it does not cause the acupuncture sensation. Both groups receive 24, 20-minute sessions over eight weeks. Participants in both groups complete a number of questionnaires at the start of the study and then again after 8, 16 and 24 weeks to find out whether their pain levels have decreased and if their joint function has improved.

What are the possible benefits and risks of participating?

It is expected that participants will benefit from a decrease in pain and improved function. The risks of participation are minimal. Occasionally, acupuncture can make people feel nauseous or experience a temporary increase in pain either during or after treatment. Rare side effects

during acupuncture treatment include fainting, infection and subcutaneous hematoma (pooling of blood under the skin). Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?

1. Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)
2. Beijing Friendship Hospital Affiliated to Capital Medical University (China)
3. Beijing Ji Shui Tan Hospital (China)

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

December 2015 to December 2016

Who is funding the study?

Beijing Municipal Administration of Hospitals Clinical Medicine Development of Special Funding Support (China)

Who is the main contact?

Dr Cun-Zhi Liu

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Contact information

Type(s)

Scientific

Contact name

Dr Cun-Zhi Liu

Contact details

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Additional identifiers

Protocol serial number

XMLX201607

Study information

Scientific Title

Traditional Chinese Acupuncture vs minimal acupuncture for mild to moderate Knee OsteoArthritis: a randomized controlled pilot trial

Acronym

CAKOA-I

Study objectives

Acupuncture at acupoints is more effective than minimal acupuncture in the treatment of mild-moderate knee osteoarthritis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 14/03/2016, ref: 2016BL-010-02

Primary study design

Interventional

Study design

Two-arm randomized controlled pilot trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis

Interventions

Participants are randomly allocated to one of two groups.

Intervention group: Participants are treated with Traditional Chinese Acupuncture for 8 weeks. Patients in Traditional Chinese Acupuncture group will be treated by use of 4-5 local acupuncture points from the following selection: ST34, ST35, ST 36, EX-LE2, EX-LE5, GB33, GB34, SP9, SP10, LV8 and Ahshi. Additionally, acupuncturists will select and needl 2-3 distant points from the following selection: GB31, GB36, GB39, GB41, ST40, ST41, LR3, BL60, SP6, KI3, LI4. Needles will be stimulated manually to achieve "De Qi" sensation for 10 seconds.

Control group: Participants are treated with minimal acupuncture for 8 weeks. Treatment in Minimal Acupuncture group will be performed at 6-8 non-acupuncture points. Needles will be placed at non-acupoints with a superficial puncture (2 mm in depth) to avoid "De Qi" and manual stimulation.

Both the Traditional Chinese Acupuncture and Minimal Acupuncture treatments consist of 24 sessions of 20 minutes duration, administered over 8 weeks (usually three sessions per week). Participants in both groups are followed up at the end of the intervention period (8 weeks), 16 weeks and 26 weeks.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Response rate is determined using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline and 8 weeks.

Key secondary outcome(s)

1. Pain is measured using WOMAC pain subscore at baseline, 8 weeks, 16 weeks and 26 weeks
2. Knee-joint function is measured using WOMAC functional subscore at baseline, 8 weeks, 16 weeks and 26 weeks
3. Number of emergency analgesics (Celebrex) used is recorded using Drug Use Form at 8 weeks, 16 weeks and 26 weeks
4. Quality of life is measured using the 12-Item Short Form Health Survey (SF-12) at baseline, 8 weeks, 16 weeks and 26 weeks
5. Adverse events are measured using Adverse Event Form at 8 weeks and 16 weeks

Completion date

30/12/2016

Eligibility

Key inclusion criteria

1. Age between 45 and 75 years
2. Pain in single or double knee joints for at least 6 months
3. Kellgren–Lawrence grade II or III in the last 6 months
4. Morning stiffness at most 30 minutes
5. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

45 Years

Upper age limit

75 Years

Sex

All

Key exclusion criteria

1. Surgery of the afflicted extremity or waiting for surgery
2. Knee pain induced by other conditions (bone tumor, bone fracture, acute infection, gout, etc)
3. Serious organic or psychiatric diseases (epilepsy, depression, etc.)
4. Severe coagulopathy
5. Pregnant or breast-feeding
6. History of receiving acupuncture, physical therapy, rehabilitation, analgesia, anti-inflammatory medication or cartilage nutrition agent in the past week
7. Current gastrointestinal ulcer
8. Participation in another clinical study in the past three months
9. Inadequacy for this trial

Date of first enrolment

30/04/2016

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

China

Study participating centre**Beijing Hospital of Traditional Chinese Medicine**

23 Meishuguanhou Street

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Beijing

China

100010

Study participating centre**Beijing Friendship Hospital**

36 Yong'an Road

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Study participating centre**Beijing Ji Shui Tan Hospital**

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China

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Sponsor information

Organisation

Beijing Municipal Administration of Hospitals

ROR

Funder(s)

Funder type

Government

Funder Name

Beijing Municipal Administration of Hospitals Clinical Medicine Development of Special Funding Support (code: XMLX201607)

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 Cun-Zhi Liu at lcz623780@126.com.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/12/2016	18/08/2023	Yes	No
Basic results		20/12/2017	06/02/2018	No	No