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Traditional Chinese acupuncture for mild to moderate knee osteoarthritis

Submission date
04/04/2016

Recruitment status
No longer recruiting

Registration date
04/07/2016

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 needels 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Two-arm randomized controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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

Overall study start date
01/12/2015

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

Age group
Adult

Lower age limit
45 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
42

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
Dongcheng District
Beijing
China
100010

Study participating centre
Beijing Friendship Hospital
36 Yong'an Road
Xicheng District
Beijing
China
100050

Study participating centre
Beijing Ji Shui Tan Hospital
31 Xinjiekou E Road
Xicheng District
Beijing
China
100000

Sponsor information

Organisation
Beijing Municipal Administration of Hospitals

Sponsor details
70 Zaolin Front Street
Xicheng District
Beijing
China
100035

Sponsor type
Government

ROR
https://ror.org/04baakq55

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/03/2017

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?
Basic results		20/12/2017	06/02/2018	No	No
Protocol article		13/12/2016	18/08/2023	Yes	No