

# A Randomised Controlled Trial (RCT) on Acupuncture Safety/Efficacy in Knee Osteoarthritis

<b>Submission date</b> 14/07/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/10/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/08/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Brian M. Berman

### Contact details

2200 Kernan Drive  
Centre for Integrative Medicine  
Baltimore, Maryland  
United States of America  
21207  
+1 410 448 6871  
bberman@compmed.umm.edu

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00010946

Secondary identifying numbers

## Study information

### Scientific Title

### Study objectives

Added 18/08/09:

The goal of this research is to determine the efficacy and safety of Traditional Chinese Acupuncture (TCA) in patients with osteoarthritis of the knee. A three arm randomised controlled trial (RCT) using sham TCA, true TCA, and an education/attention comparison group is proposed. The primary hypothesis to be tested is that patients randomised to true TCA will have significantly more improvement in pain and function as measured by the Womac Pain & Function Scales and patient global assessments than patients randomised to the sham acupuncture and education/attention control groups.

As of 18/08/09 this record has been updated. All updates can be found under the relevant field with the above update date.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

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

Osteoarthritis

### Interventions

Patients are randomised to one of three intervention groups:

1. Real Acupuncture
2. Sham Acupuncture
3. Health Education

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Added 18/08/09:

Improvement in pain and function as measured by the Womac Pain & Function Scales and patient global assessments

## **Secondary outcome measures**

Added 18/08/09:

1. Determine if improvement with TCA differs between patients below age 65 vs. those aged 65 and above,
2. Determine if improvement with TCA differs by racial/ethnic group (ie., Caucasian, Black, Hispanic), and
3. Determine if improvement with TCA differs by stage of radiographic severity of knee OA at baseline (KL grade 2, 3 or 4)

## **Overall study start date**

01/09/1998

## **Completion date**

31/08/2003

# **Eligibility**

## **Key inclusion criteria**

1. 570 Males and Females aged 50 and older
2. Diagnosis of osteoarthritis of the knee (fulfilling American College of Rheumatology [ACR] criteria) for at least 6 months duration
3. At least moderate pain in the knee for most days in the last month
4. Must be taking analgesic or nonsteroidal anti-inflammatory agents for control of pain
5. Documented radiographic changes of osteoarthritis - presence of osteophyte - at the time of rheumatological screening
6. Signed informed consent

## **Participant type(s)**

Patient

## **Age group**

Adult

**Sex**

Both

**Target number of participants**

570

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/09/1998

**Date of final enrolment**

31/08/2003

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

2200 Kernan Drive

Baltimore, Maryland

United States of America

21207

**Sponsor information****Organisation**

National Center for Complementary + Alternative Medicine (NCCAM), NI of Arthritis + Musculoskeletal + Skin Diseases (NIAMS)

**Sponsor details**

NCCAM Clearinghouse

P.O. Box 7923

Gaithersburg, MD

United States of America

20898

**Sponsor type**

Not defined

**ROR**

<https://ror.org/00190t495>

# Funder(s)

## Funder type

Research organisation

## Funder Name

National Center for Complementary and Alternative Medicine (NCCAM)

## Alternative Name(s)

NCCAM

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United States of America

## Funder Name

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

## Alternative Name(s)

The National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Arthritis & Musculoskeletal & Skin Diseases, Instituto Nacional de Artritis y Enfermedades Musculoesqueléticas y de la Piel, NIAMS

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United States of America

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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	01/12/2006		Yes	No