# Integrated care in practice: Is acupuncture a useful adjunct to physiotherapy for older adults with knee pain?

Submission date 03/01/2003

Recruitment status

No longer recruiting

Registration date 03/01/2003

Overall study status

Completed

**Last Edited** 11/01/2018

**Condition category** 

Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

Statistical analysis plan

[X] Results

Individual participant data

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr EM Hay

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

H0640

# Study information

#### Scientific Title

Integrated care in practice: Is acupuncture a useful adjunct to physiotherapy for older adults with knee pain?

# **Study objectives**

To investigate whether acupuncture is a useful adjunct to advice and exercise for treating knee pain and gain insight into whether this effect is due to specific needling properties:

- 1. We will determine the additional benefit of true acupuncture when used by physiotherapists alongside advice and exercise for older people presenting to primary care with knee pain
- 2. We will evaluate sham acupuncture in the same way
- 3. We will investigate the treatment preferences and expectations of both the participants and physiotherapists participating in the study, and explore the effect of these on clinical outcome

# 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)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

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

Knee pain

#### **Interventions**

Acupuncture plus advice and exercise versus placebo acupuncture plus advice and exercise advice versus exercise alone.

#### Intervention Type

Other

#### Phase

**Not Specified** 

## Primary outcome measure

Change in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at six months.

## Secondary outcome measures

- 1. Knee-related pain
- 2. Movement and function
- 3. Pain intensity and effect
- 4. Main functional problem
- 5. Illness perceptions
- 6. Self-efficacy
- 7. Treatment preference and expectations
- 8. General health and quality of life

## Overall study start date

01/11/2003

# Completion date

31/12/2006

# **Eligibility**

# Key inclusion criteria

- 1. Male and female subjects aged 50 years and above
- 2. Pain with or without stiffness in one or both knees
- 3. Naive to acupuncture treatment (i.e., have never experienced acupuncture before for their present or any past complaints)
- 4. Considered suitable for referral to physiotherapy outpatients department
- 5. Able to read and write English, and to give full informed consent
- 6. Willing to consent to participation
- 7. Available for telephone contact

# Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

Both

# Target number of participants

350

# Key exclusion criteria

1. Potentially serious pathology (e.g. inflammatory arthritis, malignancy etc) on the basis of general practice or physiotherapy diagnosis or from past medical history

- 2. Have had a knee or hip replacement on the affected side(s)
- 3. Are already on a surgical waiting list for total knee replacement
- 4. Trial interventions are contraindicated
- 5. Have received an exercise programme, from a physiotherapist, for their knee problem within the last three months (normal recreational involvement in sport or exercise will not be an exclusion)
- 6. Received an intra-articular injection to the knee in the last six months

# Date of first enrolment

01/11/2003

# Date of final enrolment

31/12/2006

# Locations

#### Countries of recruitment

England

United Kingdom

# Study participating centre Department of Rheumatology

Stoke-on-Trent United Kingdom ST6 7AG

# Sponsor information

## Organisation

Arthritis Research Campaign (ARC) (UK)

# Sponsor details

Copeman House St Mary's Court St Mary's Gate Chesterfield Derbyshire United Kingdom

S41 7TD

info@arc.org.uk

# Sponsor type

Charity

# Website

http://www.arc.org.uk

#### **ROR**

https://ror.org/02jkpm469

# Funder(s)

# Funder type

Charity

#### Funder Name

Arthritis Research Campaign (UK)

# **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?
<u>Protocol article</u>	protocol	02/09/2004		Yes	No
Results article	results	01/09/2007		Yes	No