

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 03/01/2003	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 11/01/2018	Condition category 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

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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

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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?
Protocol article	protocol	02/09/2004		Yes	No
Results article	results	01/09/2007		Yes	No