The process of acupuncture: a randomised controlled trial and qualitative study to evaluate the relative contributions of specific and non-specific effects

Submission date	Recruitment status No longer recruiting	Prospectively registered		
31/01/2006		☐ Protocol		
Registration date 03/03/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 20/07/2010	Condition category Musculoskeletal Diseases	Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

170/03/t

Study information

Scientific Title

Study objectives

- 1. Acupuncture is superior to placebo for the treatment of Osteo-Arthritic (OA) hip or knee
- 2. Empathic approach to treatment yields superior efficacy than a non-empathic approach
- 3. A needle-type placebo has a greater effect than a non-needle placebo

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Southampton and South West Hampshire Local Research Ethics Committee (LREC) approved on the 21st of August 2003 (ref: 170/03/t)

Study design

Randomised single blind placebo controlled multi-factorial trial with a nested qualitative study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Osteoarthritis (OA)

Interventions

Patients are randomised to receive one of the following interventions:

- 1. Acupuncture which involves a course of treatment using a standardised but flexible choice of acupuncture points around the affected area and at distal points
- 2. Placebo acupuncture which involves using non-penetrating needles
- 3. Acupuncture-type treatment is also a placebo treatment and involves the use of a pseudoelectrical stimulation to acupuncture points via surface skin electrodes

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Pain measured on a VAS

Secondary outcome measures

- 1. Western Ontario and McMaster (WOMAC) University Osteoarthritis Index functional score
- 2. Nottingham Health profile

Overall study start date

01/09/2003

Completion date

01/09/2007

Eligibility

Key inclusion criteria

- 1. Subjects aged between 18 and 80
- 2. Chronic or stable pain, predominantly from a single joint (hip or knee) of known mechanical aetiology i.e. osteo-arthritis
- 3. Score an average of 30 or more on the 100 mm visual analogue scale (VAS) in the prerandomisation phase of the study
- 4. Not be on any active treatment (e.g. physiotherapy or homeopathy)
- 5. Ability to attend clinic twice a week for the duration of treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

288

Key exclusion criteria

- 1. Pregnancy
- 2. Suffering serious co-morbidity (including severe back pain)
- 3. Prolonged or current steroid use
- 4. Waiting for hip/knee revision
- 5. Patients with needle phobia or allergy to sticking plaster

Date of first enrolment

01/09/2003

Date of final enrolment 01/09/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Health Professions Southampton United Kingdom SO17 1BJ

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

Highfield Southampton England United Kingdom SO17 1BJ jbk1@soton.ac.uk

Sponsor type

University/education

ROR

https://ror.org/01ryk1543

Funder(s)

Funder type

Government

Funder Name

Department of Health (UK) - Funded Trials for Complementary Alternative Medicine (CAM) (ref: 03/12)

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?
Results article	results	30/04/2010		Yes	No