

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

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

Protocol serial number

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

Study type(s)

Quality of life

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 pseudo-electrical stimulation to acupuncture points via surface skin electrodes

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Pain measured on a VAS

Key secondary outcome(s))

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

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 pre-randomisation 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

School of Health Professions
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation

University of Southampton (UK)

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

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