Longer term clinical and economic benefits of offering acupuncture to patients with chronic low back pain

Submission date Recruitment status Prospectively registered 25/04/2003 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 25/04/2003 Completed [X] Results [] Individual participant data Last Edited Condition category Musculoskeletal Diseases 26/08/2009

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.ftcm.org.uk/low_back_pain.htm

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 HTA 96/40/07

Study information

Scientific Title

Acronym

YACBAC

Study objectives

Acupuncture is widely used in NHS primary care for a variety of pain related conditions. Evidence of the clinical cost effectiveness of its use in this context is sparse, particularly relating to its longer term effectiveness in the relief of chronic pain. More research is needed to ensure the appropriate use of NHS resources. The proposed study is a pragmatic randomised controlled trial (n=200) to evaluate the longer term clinical and economic benefits of offering acupuncture to patients assessed as suitable for primary care management with reported low back pain of more than four weeks duration. The study aims to test the hypothesis that a population of patients offered traditional acupuncture for chronic low back pain gain as much or more relief from pain as those offered normal management only by their GP, for equal or less cost. The study aims to provide appropriate evidence for future NHS purchasing decisions. The research is a collaboration between a University research department, and accredited Acupuncture College and Research Foundation and a GP consortium. It builds on previously completed work, including a pilot of the outcome measures proposed and the feasibility of the GP referral service to traditional acupuncture treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

A pragmatic, two parallel group, 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

Chronic low back pain

Interventions

- 1. Traditional Chinese acupuncture, up to 10 treatments
- 2. Standard care offered by GP only

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Relief of chronic pain
- 2. Cost effectiveness

Secondary outcome measures

Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, and safety and acceptability of acupuncture care.

Overall study start date

12/04/1999

Completion date

11/05/2003

Eligibility

Key inclusion criteria

Patients with low back pain. Age 20-65 years with low back pain or sciatica, greater than 4 weeks and less than 12-months pain this episode

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

Past spinal surgery, severe or progressive motor weakness or central disc prolapse, possible spinal pathology (eg carcinoma)

Date of first enrolment

12/04/1999

Date of final enrolment

11/05/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Health Care

Leeds United Kingdom LS2 9UT

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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?
Other publications	HTA monograph	01/08/2005		Yes	No
Other publications	cost effectiveness analysis	23/09/2006		Yes	No
Results article	main results	23/09/2006		Yes	No