

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/08/2009	<b>Condition category</b> 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

## Study website

[http://www.ftcm.org.uk/low\\_back\\_pain.htm](http://www.ftcm.org.uk/low_back_pain.htm)

## Contact information

### Type(s)

Scientific

### Contact name

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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

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## Sponsor information

**Organisation**

Department of Health (UK)

**Sponsor details**

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**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?
<a href="#">Other publications</a>	HTA monograph	01/08/2005		Yes	No
<a href="#">Other publications</a>	cost effectiveness analysis	23/09/2006		Yes	No
<a href="#">Results article</a>	main results	23/09/2006		Yes	No