# Acupuncture for depression: a pilot for a randomised controlled trial

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
22/02/2007		[X] Protocol	
Registration date	Overall study status Completed Condition category	Statistical analysis plan	
04/04/2007		Results	
Last Edited		Individual participant data	
28/08/2018	Mental and Behavioural Disorders	☐ Record updated in last year	

### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

Dr Hugh MacPherson

#### Contact details

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# Additional identifiers

# Protocol serial number

N/A

# Study information

### Scientific Title

Acupuncture for depression: a pilot for a randomised controlled trial

# **Study objectives**

Aim: to conduct a pilot for a randomised controlled trial that will evaluate the effectiveness and cost-effectiveness of acupuncture for depression, when provided as adjunct to usual General Practitioner (GP) care.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the York Local Research Ethic Committees (York LREC) on the 4th January 2007 (ref: 06/Q1108/56).

### Study design

A pilot randomised controlled trial with three arms: acupuncture and non-directive counselling as adjuncts to usual care, and usual care alone

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

**Depression** 

### **Interventions**

Participants will receive one of the following:

- 1. Acupuncture and usual care
- 2. Non-directive counselling and usual care
- 3. Usual care alone

## Intervention Type

Other

#### Phase

**Not Specified** 

# Primary outcome(s)

**Beck Depression Inventory** 

# Key secondary outcome(s))

- 1. PHQ-9 questionnaire
- 2. Short Form health survey (SF-36) bodily pain sub-scale
- 3. European Quality of life (EQ-5D) questionnaire
- 4. Well-Being Questionnaire 12

# Completion date

21/02/2008

# **Eligibility**

### Key inclusion criteria

- 1. Patients who are being managed in primary care
- 2. Patients who have consulted their GP and have been diagnosed with depression
- 3. A depression score of 10 or above on the Patient Health Questionnaire 9 (PHQ9)
- 4. A Diagnostic Statistical Manual of mental disorders fourth edition (DSM IV) based screening instrument for depression
- 5. Are over eighteen years of age

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

- 1. Diagnosed with terminal illness
- 2. Mobility issues: cannot travel to appointments
- 3. Involved with other research projects
- 4. Dementia, learning difficulties, and communication problems
- 5. Currently receiving acupuncture or counselling
- 6. Cannot speak sufficient English to communicate with a counsellor or acupuncture practitioner
- 7. Alcohol or substance abuse problems
- 8. Received a diagnosis of bipolar disorder, psychosis, or personality disorder

### Date of first enrolment

22/02/2007

### Date of final enrolment

21/02/2008

# Locations

### Countries of recruitment

United Kingdom

England

Study participating centre
Department of Health Sciences
York

United Kingdom YO10 5DD

# Sponsor information

### Organisation

University of York (UK)

### **ROR**

https://ror.org/04m01e293

# Funder(s)

# Funder type

Government

### Funder Name

Department of Health (UK)

# **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?
Protocol article	protocol	09/01/2009		Yes	No