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 04/04/2007 Last Edited	Overall study status Completed Condition category Mental and Behavioural Disorders	Statistical analysis plan	
		Results	
		Individual participant data	
28/08/2018		☐ Record updated in last year	

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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 measure

Beck Depression Inventory

Secondary outcome measures

- 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

Overall study start date

22/02/2007

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

Age group

Adult

Sex

Both

Target number of participants

40

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

England

United Kingdom

Study participating centre Department of Health Sciences

York United Kingdom YO10 5DD

Sponsor information

Organisation

University of York (UK)

Sponsor details

(c/o Ms Sue Final)
Research Support Office
University of York
Heslington
York
England
United Kingdom
YO10 5DD
+44 (0)1904 434401
smf3@york.ac.uk

Sponsor type

University/education

Website

http://www.york.ac.uk/

ROR

https://ror.org/04m01e293

Funder(s)

Funder type

Government

Funder Name

Department of Health (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?
Protocol article	protocol	09/01/2009		Yes	No