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Acupuncture for depression: a pilot for a randomised controlled trial

Submission date	Recruitment status	[ ] Prospectively registered
22/02/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/04/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] 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

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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
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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