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Acupuncture, Counselling, and Usual GP care for Depression (ACUDep)

Submission date	Recruitment status	[ ] Prospectively registered
09/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/06/2014	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.frtcm.org/depression.htm

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, Counselling, and Usual GP care for Depression (ACUDep): a randomised controlled trial to evaluate effectiveness and cost-effectiveness

Acronym
ACUDep

Study objectives
The primary aim is to determine the clinical and cost effectiveness of short courses of either acupuncture or counselling for depression when compared to usual GP care. A secondary aim is to determine whether acupuncture is more effective than counselling, and to explore patients' experiences of these two interventions for comparative purposes.

Please note, as of 12/04/2011 the anticipated end date for this trial has been updated from 30 /09/2013 to 11/04/2011 as recruitment was completed earlier than expected. Follow up data is now being collected.

Ethics approval required
Old ethics approval format

Ethics approval(s)
York Research Ethics Committee, Learning and Research Centre approved on the 1st October 2009 (ref: 09/H1311/75)

Study design
Randomised three-arm active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Karen Overend [ko501@york.ac.uk] to request a patient information sheet

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

Interventions
Patients allocated to the acupuncture and counselling groups will receive the offer of 12 sessions on a weekly basis.

The participating acupuncturists will be members of the British Acupuncture Council who have been qualified for at least three years. The acupuncture treatments will be performed according to a treatment protocol already developed for this purpose and tested in our pilot. This will allow for each patient having a customised treatment within a standardised theory-driven framework.

Counselling will be provided by members of the British Association of Counselling and Psychotherapy using primarily a non-directive approach. A manualised protocol, which was developed for the pilot, will set the parameters for the counselling. Counsellors will use empathy and advanced listening skills to help clients express feelings, clarify thoughts, and reframe difficulties, but they will not give advice or set homework.

Usual GP care will continue to be available to all patients according to need, and will be monitored in all three groups for comparative purposes.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The Patient Health Questionnaire-9 (PHQ-9) at three months, with an evaluation of whether there is an overall benefit over the twelve months. We will use the correlation between the PHQ-9 and Beck Depression Inventory-II (BDI-II) at baseline and 12 months to determine equivalent BDI-II scores at subsequent timepoints.

Secondary outcome measures
1. SF-36 Bodily Pain Subscale
2. EQ-5D
3. CARE (Consultational and Relational Empathy measure)
4. We will also collect data on NHS resource use and patients' private costs

Overall study start date
01/11/2009

Completion date
11/04/2011

Eligibility

Key inclusion criteria
1. Patients over 18 who have consulted their GP for depression
2. Participants must also be still be depressed at the time of recruitment, with a score of 20 or above on the Beck Depression Inventory-II

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
640

Key exclusion criteria
1. Patients who are receiving acupuncture or counselling sessions
2. Terminal illness
3. Haemophilia
4. Hepatitis
5. Human immunodeficiency virus (HIV)
6. Pregnancy
7. Confounding psychiatric condition:
7.1. Bipolar disorder
7.2. Postpartum depression
7.3. Adjustment disorder
7.4. Psychosis
7.5. Personality disorder
8. Suffered a close personal bereavement
9. Given birth during the previous 12 months
10. Because of the specific demands of this study in terms of the need to fully comprehend detailed information, to complete questionnaires, to understand and converse readily with English speaking acupuncturists and counsellors, and to permit physical contact, we intend to exclude patients who have a significant learning disability, who are unable to converse in English, or who have dementia

Date of first enrolment
01/11/2009

Date of final enrolment
11/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Complementary Medicine Research Group
York
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/04m01e293

Funder(s)

Funder type
University/education

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grants

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?
Results article	results	01/05/2013		Yes	No
Results article	results	05/06/2014		Yes	No