

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

Submission date 09/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/12/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/06/2014	Condition category Mental and Behavioural Disorders	<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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Complementary Medicine Research Group

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York (UK)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes