ISRCTN44902048 https://doi.org/10.1186/ISRCTN44902048

Cognitive therapy for antenatal depression

Submission date
14/12/2009

Recruitment status
No longer recruiting

Registration date
17/02/2010

Overall study status
Completed

Last Edited
21/07/2015

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
We conducted a study to compare cognitive behaviour therapy (CBT) plus usual care with usual care. The study aimed to help women with depression recover before the end of pregnancy and to look at the feasibility of conducting a full trial. Therefore, we tested procedures for recruiting, assessing and randomly allocating women to treatment, and to assess if it was possible to provide therapy before the end of pregnancy. We also tested how well the 3 depression screening questions used by midwives at booking appointments worked.

Who can participate?
Pregnant women in North Bristol aged 16 or over and between 8 and 18 weeks pregnant were able to take part.

What does the study involve?
Women who agreed to be contacted were asked to complete some questionnaires, including a detailed assessment of depression. Women were randomly allocated either to the CBT group plus usual care or usual care. Those who received CBT were visited at home by the therapist for up to 12 sessions. Follow up assessments were repeated once more during pregnancy and again postnatally. Women who reported no low mood symptoms on the 3 depression screening questions were asked to take part in a validation study. Women who agreed were asked to complete some questionnaires.

What are the possible benefits and risks of participating?
The benefit of taking part in this study meant that the results could help midwives and GPs in the future to decide on the best treatment for women who experience low mood during their pregnancy.
Women may have found some of the questions asked during their assessment upsetting, but the researchers were able to offer support during the appointment, but they could also contact the midwives or GPs who normally provide care for them if necessary. There were no other disadvantages or risks associated with taking part in the study.

Where is the study run from?
The University of Bristol (UK).

When is the study starting and how long is it expected to run for?
The study started recruiting pregnant women in North Bristol in May 2010 until February 2011. Follow up of trial participants continued until June 2011.

Who is funding the study?
The National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) Programme.

Who is the main contact?
Dr Jonathan Evans
j.evans@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Jonathan Evans

Contact details
Academic Unit of Psychiatry
Cotham House, Cotham Hill
Bristol
United Kingdom
BS6 6JL
-
j.evans@bris.ac.uk

Additional identifiers

Protocol serial number
Version 1.0

Study information

Scientific Title
A randomised controlled trial of cognitive therapy for antenatal depression

Acronym
ANTICIPATE

Study objectives
ANTICIPATE is a pilot randomised controlled trial focusing on depression during pregnancy and aims to compare cognitive behavioural therapy (CBT) plus usual care with usual care alone. The study seeks to pilot procedures for recruiting, assessing and randomising women to treatment, and assess the feasibility and acceptability of the intervention (up to 12 sessions of one-to-one CBT to take place in women's homes or GP surgeries) during pregnancy.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Southmead Research Ethics Committee - approval pending as of 16/12/2009

Study design
Randomised controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Group 1 (Intervention arm plus usual care):
Involvement in the study will last 33 weeks. Patients will be invited to attend up to 12 once weekly one-to-one CBT sessions, 60 minutes per sessions. These are to take place at home or at GP surgery or other NHS premises - at patients' choice. During these sessions patients will work with their therapist to develop ways of managing their low mood.

Group 2 (usual care):
Involvement in the study will last 33 weeks. Patients will continue to be under the normal care of their midwife/GP for the management of their low mood. There will be no restrictions on the treatments that they can receive.

Patients will be contacted by telephone 15 and 33 weeks after entering the study to arrange follow up meetings to ask about their symptoms and to find out whether their low mood has improved or not. These meetings will normally last about 40 - 45 minutes.

Intervention Type
Behavioural

Primary outcome(s)
CIS-R diagnosis, conducted at baseline, 1st follow-up (15 weeks post-randomisation), and 2nd follow-up (33 weeks post-randomisation).

Key secondary outcome(s))
Other symptom measures (e.g. EPDS, PHQ-9, SF-12, EQ-5D), conducted at baseline, 1st follow-up (15 weeks post-randomisation), and 2nd follow-up (33 weeks post-randomisation).

Completion date
07/09/2011

Eligibility

Key inclusion criteria

1. Pregnant women in North Bristol
2. Aged 16 or over
3. Between 8 and 18 weeks pregnant
4. Screen positive on the three question depression screen
5. Meet criteria for International Classification of Diseases, version 10 (ICD-10) depression (assessed using the Clinical Interview Schedule - Revised [CIS-R] version)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Currently receiving CBT or another individual psychological therapy
2. Known to have a psychotic illness
3. Receiving care from secondary mental health services
4. Do not have sufficient English to complete questionnaires, as translation might affect the validity of the scales, and they would not be able to benefit from a talking therapy without an interpreter
5. Taking part in any other intervention trial

Date of first enrolment
01/05/2010

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Academic Unit of Psychiatry
Bristol
United Kingdom
BS6 6JL

Sponsor information

Organisation
University of Bristol (UK)

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme (ref: PB-PG-1207-15063)

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	22/01/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes