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Comparing low intensity talking therapies for antenatal depression: a feasibility trial

Submission date
05/04/2018

Recruitment status
No longer recruiting

Registration date
02/05/2019

Overall study status
Completed

Last Edited
19/06/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
One in eight women suffers from depression during pregnancy. Depression affects the mother, infant and family, so it is important to offer effective treatments that meet their needs. Currently CBT is the only widely available NHS talking treatment. Mothers in PPI groups have asked for greater treatment choice. IPC, a brief individual therapy, has important advantages over CBT because it focuses on issues relevant to women during pregnancy. These include: key relationship problems, changes in role and previous loss (e.g. miscarriage) and can involve partners. Women may be more likely to complete IPC and it may therefore work better than CBT. The aim of this study is to test whether it is possible to recruit, randomize and offer talking therapy (Interpersonal Counselling (IPC) or brief Cognitive Behavioural Therapy (CBT)) to women with depression in pregnancy, to inform whether a large trial comparing these treatments is possible.

Who can participate?
Women between 10 and 20 weeks of pregnancy who have been screened as having depression using both the EPDS and CIS-R screening tools, identified through midwife booking clinics and at ultrasound scanning appointments.

What does the study involve?
Participants are randomly allocated to receive 6 weeks of either IPC or CBT. After 12 weeks their mood, well-being, relationship satisfaction and use of health care are assessed. Participants, their partners and staff providing treatments are interviewed in order to understand whether IPC is an acceptable approach and if any changes required for the future trial design.

What are the possible benefits and risks of participating?
Pregnant women with antenatal depression will be offered talking therapy and the study will help to decide which treatment is best for women with low mood in pregnancy. Those with more severe depression will be referred for more intensive treatment and anyone who finds taking part upsetting can be referred to their midwife or GP for further help.

Where is the study run from?
The study is run from the University of Bristol and patients will be recruited in Bristol and Exeter (UK)

When is the study starting and how long is it expected to run for?
September 2018 to May 2020

Who is funding the study?
NIHR Research for Patient Benefit funding programme (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
40239

Study information

Scientific Title
Low-intensity interventions for antenatal depression: a feasibility study of a randomised controlled trial of interpersonal counselling compared to cognitive behavioural therapy

Acronym
ADAGIO

Study objectives
A trial to examine the feasibility and acceptability of conducting a full-scale RCT to compare the effectiveness of IPC compared to low-intensity CBT for mild to moderate depression during pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/11/2018, North of Scotland Research Ethics Committee (1) (Summerfield House, 2 Eday Road
Aberdeen, AB15 6RE; Tel: +44 (0)1224 558458; Email: nosres@nhs.net), ref: 239657

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Antenatal depression

Interventions
12 low-intensity practitioners working in NHS psychological treatment services will be randomised to receive training in IPC or booster training in CBT. This will be evenly split across two centres, Bristol and Exeter.

60 women with mild to moderate depression (EPDS score of 10 or more and ICD 10 criteria according to the revised Clinical Interview Schedule) will be recruited (30 at each site) at midwife clinic appointments and ultrasound scanning appointments. Women between 10 and 20 weeks of pregnancy and meeting criteria for mild to moderate depression will be randomised to receive six sessions of IPC or CBT from the trained practitioners.

Outcomes will be collected online or by telephone 12 weeks following randomisation. These will include: the Edinburgh Depression Scale (questionnaire), relationship measures (Revised Dyadic Adjustment Scale and Maternal Antenatal Attachment Scale questionnaires), health economic measures (EQ-5D-5L and ReQol10 questionnaires).

The number of sessions attended, number including the partner, whether step up to more intense psychological intervention is needed, use of medication, and use of secondary mental health services will also be recorded from practitioner records.
In-depth interviews will be conducted with women who have completed IPC (10-12 women) or CBT (5-6 women) and their partners focusing on the acceptability and perceived effectiveness of the talking therapy. Interviews will also be conducted with study decliners, where possible, to understand ways in which participation might be supported. Practitioners in the IPC arm, their supervisors and midwives, will be interviewed at the end of the intervention to focus on the acceptability, strengths and weaknesses of the intervention and recruitment process.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment rate, measured using trial documentation after 9 months of recruitment (October 2019)
2. Number of women who receive complete IPC treatment as judged by the practitioner from practitioner records at the end of the trial
3. Number of women who complete outcome data, measured 4 months after recruitment for each participant
4. Acceptability of IPC and trial design assessed using in-depth interviews at 4-6 months after recruitment
5. Supervisor’s rating of practitioner’s adherence to the IPC model at the end of the trial

Secondary outcome measures
Measured at baseline and 12 weeks after recruitment for each participant using validated tools completed on paper or online:
1. Depression symptoms are measured using Edinburgh Depression Scale (EPDS)
2. Partner satisfaction and relationships are measured using Revised Dyadic Adjustment Scales (RDAS)
3. Maternal attachment to her unborn baby is measured using Maternal Antenatal Attachment

Scale (MAAS)
4. Health-based wellbeing is measured using EQ-5D-5L
5. Wellbeing, particularly for mental health problems, is measured using ReQol-10

Overall study start date
01/09/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Women who are pregnant
2. Mild or moderate depression with or without co-morbid anxiety
3, Both primiparous and multiparous women
4. Between 10 and 20 weeks of pregnancy
5. Edinburgh Depression Scale (EPDS) score above 10
6. Mild or moderate depression according to Clinical Interview Schedule Revised (CIS-R) (Lewis et al 1992)
7. Whether or not they are taking an antidepressant

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Total final enrolment
52

Key exclusion criteria
1. Psychotic illness
2. Organic brain disorder
3. Bipolar disorder
4. Personality disorder
5. Alcohol or substance dependency
6. Those with high suicide risk judged to be in need of a more intensive intervention
7. If any women miscarry or have a termination during the trial will be offered to continue with the treatment but not included in the main analyses

Date of first enrolment
04/01/2019

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
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Sponsor information

Organisation
University of Bristol

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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Protocol planned to be published in 2019. Planned publication of the results in a high-impact peer-reviewed journal by May 2021.

Intention to publish date
01/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jonathan Evans (j.evans@bristol.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/08/2019	15/01/2021	Yes	No
Results article		15/10/2021	19/06/2023	Yes	No
Results article	Nested qualitative study	12/11/2021	19/06/2023	Yes	No