

Depression: a trial of antenatal guided self help for women

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|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Submission date 08/08/2014 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 08/08/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/08/2020 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Pregnancy does not appear to be protective against the existing or development of new mental disorders. Depression is the most common antenatal mental disorder and can have a considerable impact upon a woman and her family. To date, there has been no study of mild psychological interventions in the antenatal setting which may be more effective and cost-effective for mild and moderate depression during pregnancy. We therefore propose to modify and evaluate Guided Self Help materials for antenatal depression in women using NHS maternity services. This study aims to get initial evidence on the how effective is the Guided Self Help intervention in improving depressive symptoms and other outcomes (e.g. psychological symptoms after giving birth and quality of life) for women with antenatal depression.

Who can participate?

Adult pregnant women who are up to 26 weeks pregnant and having depressive symptoms can take part.

What does the study involve?

Pregnant women experiencing depression will be randomly allocated to either antenatal Guided Self Help (given by an NHS Psychological Wellbeing Practitioner) plus usual care, or to usual care alone. The antenatal Guided Self Help intervention has been modified from existing Guided Self Help materials used in psychological services for the treatment of depression. Modifications include addressing pregnancy-specific worries, and including sections on health issues in pregnancy and planning for parenthood. Women allocated to the this group will be seen for up to eight sessions by a Psychological Wellbeing Practitioner (including an initial assessment session); there will also be a appointment at 12 weeks after delivery. Research measures will be taken from all women before random allocation, after 14 weeks of allocation and at 12 weeks after delivery. Data will also be collected to find out if this method is cost-effective.

What are the possible benefits and risks of participating?

The opportunity to talk about symptoms with a researcher can be beneficial and, where appropriate, participants will be encouraged to discuss concerns with their midwife and given information on sources of help and support, which may be helpful in managing their situation. Some participants may find that being asked questions about their mental health and wellbeing

is sensitive, and the potential for the interview to bring up these feelings is described on the Participant Information Sheet. At the beginning of the interview, participants will be asked if there is anyone they would like the researcher to contact for support if they become distressed. Participants will be closely monitored during interviews for signs for distress and appropriate action will be taken. If there are concerns about the health and wellbeing of participants or their children at the end of the interview, participants will be asked if they would like any of the information they disclosed to be conveyed to their clinic midwife.

Where is the study run from?

The study is being run from Kings Health Partners (UK)

When is the study starting and how long is it expected to run for?

October 2014 to June 2017

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Ms Kylee Trevillion

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Contact information

Type(s)

Scientific

Contact name

Ms Kylee Trevillion

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Depression: an exploratory parallel-group randomised controlled trial of Antenatal guided self help for Women (DAWN)

Acronym

DAWN Trial

Study objectives

Women with mild or moderate antenatal depression treated with Guided Self Help will have significantly lower Edinburgh Postnatal Depression Scale (EPDS) depressive symptoms at 14 weeks post-randomisation compared with women with mild or moderate antenatal depression receiving usual care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London-Camberwell St Giles, 11/06/2014, ref: 14/LO/0597

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Mental Health, Reproductive health and childbirth; Subtopic: Depression, Reproductive Health and Childbirth (all Subtopics); Disease: Depression, Reproductive Health & Childbirth

Interventions

Women will be randomly assigned to:

1. Guided Self Help (delivered by Psychological Wellbeing Practitioners) plus usual care
2. Usual care alone (i.e., treatment as usual)

Guided Self Help, Details: Existing Guided Self Help materials used in psychological services for the treatment of depression are being modified for pregnancy. The Guided Self Help (with usual care) intervention for antenatal depression is being delivered by NHS Psychological Wellbeing Practitioners (PWP). The intervention comprises an initial session at the beginning of therapy, followed by up to eight 30-minute sessions. An additional session will also be conducted, at six to eight weeks post-delivery (i.e. before the post-delivery research outcomes are collected)

Intervention Type

Other

Phase

Phase II

Primary outcome measure

Depression, measured using the Edinburgh Postnatal Depression Scale - depressive symptoms at baseline and 14 weeks

Secondary outcome measures

1. Anxiety, measured using the Generalized Anxiety Disorder Scale (GAD-7) at baseline and 14 weeks
2. Depression, measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and 14 weeks and the Edinburgh Postnatal Depression Scale and Whooley items at 3 months post-delivery
3. Health-related quality of life, measured using the Short Form Health Survey (SF-6D) at baseline, 14 weeks and 3 months post-delivery
4. Service contacts, measured using the Adult Service Use Schedule at 14 weeks and 3 months post-delivery
5. Parenting stress, measured using the Postpartum Bonding Questionnaire at 3 months post-delivery

Overall study start date

30/10/2014

Completion date

30/06/2017

Eligibility

Key inclusion criteria

1. Pregnant women, up to 26 weeks gestation
2. Aged 16 years or older
3. Meeting the criteria for DSM--IV depression

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Planned Sample Size: 110; UK Sample Size: 110

Total final enrolment

53

Key exclusion criteria

1. Pregnant women who are unable to complete the trial questionnaires/workbook in English or provide informed consent
2. Have psychosis, borderline personality disorder, a current eating disorder, current post-traumatic stress disorder, or suicidality and/or are receiving secondary mental health care, psychological therapies or antidepressants

Date of first enrolment

30/10/2014

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Croydon Health Services

530 London Road

Croydon

London

United Kingdom

CR7 7YE

Study participating centre

St Thomas' Hospital

10th floor North Wing

Westminster Bridge Road

London

United Kingdom

SE1 7EH

Study participating centre

University Hospital Lewisham

Lewisham High Street
London
London
United Kingdom
SE13 6LH

Study participating centre**South London and Maudsley NHS Foundation Trust**

Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Study participating centre**King's College Hospital**

Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation

King's College London (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 18/10/2016 | | Yes | No |
| Results article | results | 01/01/2020 | 07/08/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |