ISRCTN83768230 https://doi.org/10.1186/ISRCTN83768230

# Depression: a trial of antenatal guided self help for women

**Submission date**
08/08/2014

**Recruitment status**
No longer recruiting

**Registration date**
08/08/2014

**Overall study status**
Completed

**Last Edited**
07/08/2020

**Condition category**
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

17048

# 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 (PWPs). 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 |