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A study to support women with mild to moderate anxiety in pregnancy

Submission date
15/03/2022

Recruitment status
No longer recruiting

Registration date
18/03/2022

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Each year in the UK about 750,000 women use midwifery services, and 14% will experience symptoms of anxiety. Anxiety disorders are associated with postnatal depression, low birthweight, premature birth and developmental and behavioural problems in children. For women with mild-moderate anxiety, psychological support may help reduce anxiety and prevent an escalation of symptoms. A preliminary study (RAPID-1) was completed in 2017. The intervention design followed the Medical Research Council (MRC) framework and was informed by psychological theory, systematic review evidence and expert and public involvement. RAPID-1 was the first midwife-led intervention to be evaluated for pregnant women with symptoms of mild to moderate anxiety. The preliminary study demonstrated the intervention could be integrated within routine maternity care and women considered that they benefitted from participating. The aim of the RAPID-2 study is to test the feasibility of conducting a trial to examine the effectiveness of a midwife-facilitated intervention for pregnant women with symptoms of mild to moderate anxiety

Who can participate?
Women aged 18 years and over, about 16-20 weeks pregnant with no previous births, with symptoms of mild to moderate anxiety, attending for accessing maternity care in the participating NHS Trusts

What does the study involve?
Women are randomly allocated to receive or to not receive the RAPID support. Women receiving RAPID support will be invited to attend discussion groups once per fortnight over 12 weeks. A midwife and maternity support worker will help run the groups. Women will also have a choice of self-help materials to use between groups. Groups will be held online or in healthcare centres and women will be able to speak one-to-one with a midwife if they wish. Women will be asked to complete questionnaires about their feelings and their situations. Women not allocated to the RAPID support will be asked to complete questionnaires about their feelings and their situations. Nothing that can identify women as individuals will be reported and names will not be used. Women will be involved in the study for around 18 weeks in total.

What are the possible benefits and risks of participating?
The researchers cannot promise the study will help the participants but the information from this study may help other women in the future. It is unlikely that there will be any drawbacks in taking part, although women may sometimes feel upset when discussing their feelings. The researchers ask that women participating in groups only share things that they are comfortable sharing. The midwife leading the group will be available to discuss any concerns.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2019 to July 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Kerry Evans, kerry.evans1@nottingham.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Kerry Evans

ORCID ID
http://orcid.org/0000-0002-1381-9168

Contact details
Nottingham University Hospitals Trust
Research and Innovation
Nottingham
United Kingdom
NG7 2UH
+44 (0)7596783920
kerry.evans1@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
294369

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
21OB011, IRAS 294369, CPMS 51712

Study information

Scientific Title
The RAPID 2 study: Reducing Anxiety in Pregnancy: Intervention Development phase 2. A feasibility study of a midwife-facilitated supportive intervention versus standard care for nulliparous pregnant women with symptoms of mild to moderate anxiety

Acronym
RAPID 2

Study objectives
The aim of the study is to test the feasibility of conducting a trial to examine the effectiveness of a midwife-facilitated intervention compared with usual care for pregnant women with symptoms of mild to moderate anxiety

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2022, East Midlands - Derby Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 1048211; derby.rec@hra.nhs.uk), ref: 22/EM/0018

Study design
Multicentre feasibility open pragmatic cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pregnant women with symptoms of mild to moderate anxiety

Interventions
Clusters will be randomly allocated to intervention groups and control groups within each stratum. Randomisation will be performed by the statistical team at the Derby Clinical Trials

Support Unit. Random allocation will be conducted by Derby Clinical Trials Support Unit using a web-based system. Neither the cluster site, participant nor the facilitator can be blinded to allocation status.

Participants in the intervention group will receive treatment as usual (as described for control group) plus the RAPID 2 intervention, comprising three components:
1. One-to-one pre-group meeting with the midwife facilitator. Facilitators will receive training to help them support women with symptoms of mild to moderate anxiety in pregnancy and facilitate group sessions.
2. Group discussion sessions facilitated by a midwife and midwifery support worker. Four facilitated groups plus two peer-led groups will take place over a 12-week period (every fortnight). Groups will last approximately 90 minutes. Discussion topics will be suggested and agreed by the group. Individual midwife support will be available before and after groups.
3. A choice of self-help materials to be accessed between groups. The choice of materials is based on service user preferences and relevance in a UK healthcare context. Materials cover cognitive skills, mindfulness meditation and/or relaxation.

Control group participants will receive usual maternity care (treatment as usual, TAU). The exact component of usual antenatal care varies across settings, but always includes routine midwife appointments and access to obstetric and specialist perinatal mental health services, as required. Components which may not be available in all sites include emotional or social support interventions and low-level psychological services such as IAPT. Control group participants will be asked to complete the same pre-intervention, mid-point and post-intervention data collection questionnaires as the intervention group and will be offered the same choice to complete questionnaires digitally or by hand.

The duration of participant involvement will be 18 weeks. The intervention duration is 12 weeks.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment, retention and completion rates measured at recruitment using the:
1.1. The number of women accessing the site and completing eligibility screening
1.2. The number of eligible women
1.3. The number of women who consent to participate
4. Women's and facilitators' views on participating in the intervention and the acceptability and experiences of random allocation to a usual care group, assessed using face-to-face semi-structured interviews conducted in the community, women's homes or via video conferencing platforms (women's preference and following local and national guidance re: COVID-19 following Sponsors Standard Operating Procedures) at post-intervention (follow-up)

Secondary outcome measures
Measured at baseline, 7 and 13-14 weeks:
1. Anxiety assessed using the Generalised Anxiety Disorder scale (GAD-7)
2. Anxiety and depression assessed using the Edinburgh Postnatal Depression Scale (EPDS)
3. Pregnancy-related anxiety assessed using the Pregnancy Related Anxiety Questionnaire - Revised (PRAQ-R)
4. Quality of life assessed using the Short-Form Health Survey (SF-12)
5. Social support assessed using the Multidimensional Scale for Perceived Social Support (MSPSS)
6. Service and support use assessed using the Client Service Receipt Inventory (CSRI)

Overall study start date
10/04/2019

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Women attending for or accessing maternity care in the study site NHS Trusts at approximately 16-20 weeks of pregnancy
2. Nulliparous pregnant women aged 18 years or older at the time of enrolment (no upper age limit)
3. Self-reported symptoms of mild to moderate anxiety
4. Able to read, write and speak the English language

Self-reported symptoms of anxiety:
A study website will present potential participants with an example of the GAD-7 scale and advise that women with scores between 3 - 14 are suited to participate in the study. Women will be advised to contact their GP or community midwife if they feel they require further assessment and support (current practice guidelines). Participants with a GAD-7 score of 15 or more will be thanked for their interest and advised that the type of intervention the study is aiming to assess may not be suited to them. A score of 15 or more may indicate severe anxiety (Spitzer et al. 2006) and these women will be advised to contact their GP or community midwife for further assessment and support.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
4 clusters of 50 participants

Total final enrolment
60

Key exclusion criteria
Pregnant women receiving treatment for a severe and enduring mental health condition

Date of first enrolment
23/02/2023

Date of final enrolment
21/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
Mansfield Road
Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
Northampton General Hospital
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre
The Dudley Group NHS Foundation Trust
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
c/o Jennifer Boston
Head of Research Governance and Quality
Nottingham
England
United Kingdom
NG7 2UH
+44 (0)1159709049
researchsponsor@nuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nuh.nhs.uk/research-contact-us/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
Health Education England

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
Following completion of the trial, the data will be analysed, and a Final Study Report prepared for submission to the Health Education England (HEE)/National Institute for Health Research (NIHR) Integrated Clinical Academic (ICA) awards committee. The report will be published on the NIHR website. The trial protocol will be published following National Research Ethics Service (NRES) approvals. Dissemination will include written reports, executive summaries and presentations to healthcare providers, Clinical Commissioning Groups (CCGs), Local Maternity Systems, Integrated Care Alliances, local and national perinatal mental health networks (i.e. Maternal Mental Health Alliance [MMHA], national and international health charities (i.e. King's Fund, Mind, Beyond Blue), Royal Colleges (i.e. GPs, psychiatrists, midwives). Papers will be prepared for academic and clinical conferences and peer-reviewed journals. Participants will be offered a summary of findings to be sent via email or post

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/10/2022	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No