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A group treatment for antenatal anxiety

Submission date
21/09/2023

Recruitment status
Recruiting

Registration date
12/02/2024

Overall study status
Ongoing

Last Edited
03/12/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Up to a quarter of women struggle with serious anxiety symptoms during pregnancy. Many women will not improve without treatment, with symptoms continuing postnatally and for some, leading to depression. High anxiety during pregnancy is related to negative outcomes in childbirth and baby development. Babies of mothers who struggle with anxiety during pregnancy can have more problems with their emotions, behaviours and cognitive development. If the mother's anxiety continues after the baby is born it can make it difficult for the mother to bond with the baby and provide the kind of care the baby needs. Together, the impact of untreated perinatal mental health problems cost over £8 billion each year in England. Despite the fact that anxiety problems are more common during pregnancy and have many negative effects, there is a lack of high quality research about the best way to help mothers. In the NHS most mothers with antenatal anxiety (65%) are seen in primary mental health care (IAPT), but IAPT lacks treatments that specifically address antenatal anxiety.

We will test whether CALM 1) improves anxiety in pregnant women during pregnancy; 2) has sustained benefits in the postnatal period, up to a year after the baby is born; 3) improves the relationship the parent has with the child and how the child develops and 4) is cost-effective for the NHS to deliver. We will also interview parents who completed CALM to see which parts helped them the most, and we will ask care providers about the best ways to ensure CALM fits within the NHS.

Who can participate?
Any woman or birthing person over the age of 18 who scores 8 and above on the GAD-7.

What does the study involve?
Eligible participants will be randomised to either receive the intervention and treatment as usual or solely treatment as usual. Those in the intervention will receive a 4-session group based online intervention delivered by healthcare and psychological practitioners. The intervention includes partners or a close support and the group encourages peer support. All participants will be asked to complete questionnaires at 6 timepoints (at the start, 22 and 32 weeks pregnant, 2/6 /12 months post birth).

What are the possible benefits and risks of participating?
There is a lack of information about the effectiveness and long-term benefits of a group

treatment for antenatal anxiety compared to usual care. Regardless of the group you will be randomised into, your input in the clinical trial will contribute to the evidence around what treatment is effective in targeting pregnancy-related anxiety. If you do decide to take part, as a thank you gesture we will offer you a voucher.

We do not expect there are any disadvantages or risks to you. All the sessions will be arranged at a time to suit you and your partner. You may feel anxious before or tired after taking part in the sessions or while completing the questionnaires, but we will do everything we can to minimise or prevent this.

Where is the study run from?
The Universities of Exeter, Manchester, Cambridge, and Birmingham are leading the recruitment. This trial also has academics from Imperial College London, University of Bath, Anna Freud Centre and Kings College London. It is sponsored by Devon Partnership NHS Trust.

When is the study starting and how long is it expected to run for?
September 2023 to August 2027

Who is funding the study?
National Institute of Health Research - Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Antoinette Davey, antoinette.davey@exeter.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333463

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
29369, IRAS 333463, CPMS 60522

Study information

Scientific Title
ACORN-II: A multi-site randomised COntrolled trial to evaluate the impact of a group tReatment for aNtenatal anxiety

Acronym
ACORN-II

Study objectives
The primary objective is to test whether CALM + Treatment as usual (TAU) reduces anxiety in pregnant women relative to TAU alone. We will also assess whether CALM + TAU has sustained benefits up to a year after the baby is born compared to TAU alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/01/2024, South West - Cornwall & Plymouth Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8143; cornwallandplymouth.rec@hra.nhs.uk), ref: 24/SW/0013

Study design
Group sequential multi-centre parallel arm individually randomized controlled trial with internal pilot interim monitoring for futility and economic and process evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Antenatal anxiety

Interventions
Potential participants will be screened for anxiety at first-trimester scanning clinics. If individuals score 8 and above on the GAD-7, they will be eligible for the trial.

Eligible participants who consent will be randomly allocated on a 1:1 basis to CALM + TAU or TAU only using permuted block randomisation which will be stratified by site and anxiety diagnosis prepregnancy versus de novo antenatal anxiety. Randomisation will be delivered by a web-based randomisation system (integrated within the trial REDCap system).

The CALM intervention comprises four 2-hour online group sessions delivered to both the pregnant woman/birthing person and their partner and one 2-hour postnatal reunion. It is delivered by a healthcare and psychological practitioner. The intervention focuses on strategies that: (1) reduce avoidance associated with worry, (2) improve the ability to tolerate uncertainty that contributes to anxious worry in the perinatal period and (3) improve relationship satisfaction through joint communication skills about how to manage worry together.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety will be measured using the Generalised Anxiety Disorder -7 PROM at baseline, 22 & 32 weeks pregnant, and postnatally at 3, 6, and 12 months.

Key secondary outcome(s))
1. Antenatal anxiety measured using Pregnancy-Related Anxiety Questionnaire – Revised 2 (PRAQ-R2) at baseline, 22 weeks and 32 weeks
2. Depression using Patient Health Questionnaire-9 (PHQ-9) at baseline, 22 & 32 weeks pregnant, and postnatally at 3, 6, and 12 months.
3. Relationship adjustment measured using Revised Dyadic Adjustment Scale (DAS) at baseline, 22 and 32 weeks pregnant.
4. Health related quality of life measured using EuroQol-5 Dimensions-5 Level (EQ-5D-5L) at baseline, 22 & 32 weeks pregnant, and postnatally at 3, 6, and 12 months.
5. Service use measured using Adult Service Use Schedule (AD-SUS) at baseline, 32 weeks pregnant and 12 months postnatal.
6. Infant behaviour and temperament measured using Infant Behavior Questionnaire – Revised (IBQ-R) at 6 months postnatal.
7. Perceptions of childbirth measured using Maternal Perceptions of Support and Control in

Birth (SCIB) at 3 months postnatal.
8. Parent and infant interaction measured using 10-minute videoed interaction and coded using the well-validated NICHD parent-infant sensitivity, intrusiveness scales at 12 months postnatal.
9. Social, emotional and behavioural problems in the infant measured using Brief Infant Toddler Social and Emotional Assessment (BITSEA) at 12 months postnatal.
10. Child development measured using Ages and Stages 3rd edition at 12 months postnatal.

Completion date
31/08/2027

Eligibility

Key inclusion criteria
Pregnant women and birthing persons aged 18+ years who score above clinical threshold (8 or more) (on a standard anxiety screening measure (GAD-7)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Actively suicidal
2. Substance abuse
3. Psychosis
4. Have childbirth-related PTSD (i.e., individuals eligible to receive PTSD treatment in maternal mental health services)
5. Receiving current psychological treatment for anxiety at baseline interview

Date of first enrolment
01/05/2024

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
St Mary's Hospital
Hathersage Rd
Manchester
England
M13 0JH

Study participating centre
Royal London Hospital and Associated Community Services NHS Trust
The Royal London Hospital
Whitechapel
London
England
E1 1BB

Study participating centre
Homerton Hospital
Homerton Row
London
England
E9 6SR

Study participating centre
Birmingham Women's NHS Foundation Trust
Birmingham Womens Hospital

Metchley Park Road
Birmingham
England
B15 2TG

Sponsor information

Organisation
Devon Partnership NHS Trust

ROR
https://ror.org/04fkxrb51

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	04/12/2023	29/01/2024	No	Yes
Participant information sheet	version 1.0	07/11/2023	29/01/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes