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The ACORN study: Coping and Relaxation in Pregnancy

Submission date
29/10/2014

Recruitment status
No longer recruiting

Registration date
29/10/2014

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims

For many women, pregnancy is a positive experience. However, for some, pregnancy can intensify existing areas of anxiety and introduce new areas of concern. For example, women have reported becoming more worried about the support available to them and feeling anxious about their pregnancy, birth and parenting. These feelings can have a considerable impact on the woman and her developing foetus. Babies of mothers who have had higher than average levels of anxiety during pregnancy have more problems in their emotional, behavioural and cognitive development. These same women are also at an increased risk of postnatal anxiety and depression, both of which make it challenging for the mother to provide care for her baby, and can interfere with the formation of a secure emotional bond between mother and infant. Despite the fact that anxiety is common during pregnancy and may have adverse consequences for the mother and her baby, there is very little research into the best and most acceptable ways of helping women. However, a guided self-help intervention designed to help parents prepare for the emotional aspects of parenting has recently been tested in Australia and shown to reduce anxiety in expectant mothers. In order to reach the greatest number of women in an effective and cost effective fashion, we plan to adapt this intervention to be delivered to women with elevated anxiety by midwives in the context of routine antenatal care in the UK. In order to do this, we will first trial the intervention with a small group of women and gain feedback from them in order to understand what modifications are needed. The findings from this phase will be used to guide the final refinement of a brief psychological intervention to reduce anxiety in pregnant women which will then be tested for feasibility and acceptability in a randomised controlled trial. Our primary aims are therefore to develop a brief, widely deliverable intervention to improve symptoms of anxiety in pregnant women and to test its feasibility and acceptability to pregnant women and their partners in a randomised controlled trial.

What does the study involve?

The programme involves attending three group sessions led by midwives. The sessions will be in the evening at three-week intervals. Each session will last about 1.5 hours and will take place at Queen Charlottes and Chelsea Hospital, London. We would like to involve partners as well where this is possible, but are very happy for women to come on their own if not. In these sessions participants will receive information about stress and anxiety during pregnancy, and will learn a

variety of techniques and strategies to help with these feelings. Participants will also receive a workbook called Towards Parenthood, which includes details of the information and techniques. Participants will be asked to complete some questionnaires at the beginning and end of the study so we have an idea of how they are getting on. After participants have completed the group session we would like to talk to them about their experiences of the group intervention and being in the study. We are interested in getting feedback on all aspects of the programme and the research. This discussion will take about 30 - 60 minutes.

What are the possible benefits and disadvantages of taking part?
We are in the early stages of this research and therefore we cannot say with certainty that taking part will be of benefit to participants. However, the programme has been used in research studies previously and parents have found it helpful. It has been shown to reduce stress and anxiety in expectant parents. The disadvantages of taking part are likely to be small. Participants will need to put aside time for the group sessions (about 1.5 hours), which will be in the evening, and the follow up discussion (about 30 - 60 minutes). The midwives and researchers are experienced and specially trained for the study, and if during the sessions or discussions participants were to feel uncomfortable or distressed for any reason, they would respond sensitively and only continue if the participant was happy to do so.

Where is the study run from?
Participants will be recruited from Queen Charlotte's and Chelsea Hospital, London. The group intervention will also take place at this location.

When is the study starting and how long is it expected to run for?
October 2014 to November 2016

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

Who is the main contact?
Dr Paul Ramchandani
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(updated 09/08/2021, previously: p.ramchandani@imperial.ac.uk)

Study website
http://www.acornstudy.org/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17669

Study information

Scientific Title
Adapting and testing a brief intervention to reduce maternal anxiety during pregnancy

Acronym
ACORN

Study objectives
What is the acceptability and feasibility of delivering a brief midwife-led psychological intervention to reduce symptoms of anxiety in women in the antenatal period?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Riverside, 15/04/2014, ref. 14/LO/0339

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
Please click on the “What will I have to do” tab at http://www.acornstudy.org/

Health condition(s) or problem(s) studied
Topic: Mental Health, Reproductive health and childbirth; Subtopic: Anxiety, Reproductive Health and Childb (all Subtopics); Disease: Anxiety, Reproductive Health & Childbirth

Interventions
1. Intervention:
This study will adapt an existing guided self-help psychological intervention, Towards Parenthood (Milgrom et al, 2011), to be delivered in a group format, designed to be integrated within routine UK antenatal care. It will comprise of 3 midwife-led sessions which aim to support expectant parents in developing effective coping skills to manage anxiety and the transition to parenthood. Participants will also be given the Towards Parenthood workbook and there will be a postnatal follow up session.
2. Usual care (control group):
Women randomised to the usual care group will continue to receive their standard care for antenatal anxiety. Although there is currently no standard model of care for antenatal anxiety, this may include care provided by their GP, midwife, health visitor, local IAPT service or community mental health team.

Intervention Type
Behavioural

Primary outcome measure
Feasibility assessed by:
1. % of individuals consenting to the study
2. % completing the anxiety screening questionnaire and entering the randomisation phase
3. The number of sessions completed by those in the treatment arm
4. % completing the outcome measures at post-treatment follow-up

Secondary outcome measures

1. Generalised Anxiety Disorder Questionnaire (GAD-7). Timepoint(s): Pre-treatment, Post-treatment, Post-workbook (8 weeks after the end of treatment), 8 weeks postnatally
2. Edinburgh Postnatal Depression Scale (EPDS). Timepoint(s): Pre-treatment, Post-treatment, Post-workbook (8 weeks after the end of treatment), 8 weeks postnatally
3. Between group pre-post effect sizes and confidence intervals on the GAD-7 and EPDS. Timepoint(s): Post-treatment
4. Pregnancy-specific worries. Timepoint(s): Pre-treatment, Post-treatment, Post-workbook (8 weeks after the end of treatment), 8 weeks postnatally
5. Dyadic Adjustment Scale. Timepoint(s): Pre-treatment, Post-treatment, Post-workbook (8 weeks after the end of treatment), 8 weeks postnatally
6. EQ-5D-3L; Timepoint(s): Pre-treatment, Post-treatment, Post-workbook (8 weeks after the end of treatment), 8 weeks postnatally
7. Adult service use schedule (AD-SUS). Timepoint(s): Pre-treatment, Post-treatment, Post-workbook (8 weeks after the end of treatment), 8 weeks postnatally
8. Parental Bonding Questionnaire. Timepoint(s): 8 weeks postnatally
9. Infant Sleep Questionnaire. Timepoint(s): 8 weeks postnatally
10. Infant Behaviour Questionnaire. Timepoint(s): 8 weeks postnatally

Overall study start date
20/10/2014

Completion date
11/11/2016

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. First-time parents in second trimester of pregnancy
3. Women who score in the top quartile of population norms on screening measure for anxiety symptoms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

Key exclusion criteria
1. Insufficient understanding of English
2. Significant illness/disability in parent that would make it difficult for them to take part

Date of first enrolment
11/11/2014

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Charlotte's and Chelsea Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre
St Mary's Hospital
Praed Street
Paddington
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Central and Northwest London NHS Foundation Trust (UK)

Sponsor details
Trust Headquarters
Stephenson House
75 Hampstead Road
London
England
United Kingdom
NW1 2PL

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/05drfg619

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
To be confirmed at a later date

Intention to publish date
31/12/2021

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	22/03/2016		Yes	No
HRA research summary			28/06/2023	No	No