

# The ACORN study: Coping and Relaxation in Pregnancy

<b>Submission date</b> 29/10/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/08/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Contact name**

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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?
<a href="#">Protocol article</a>	protocol	22/03/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No