Participant Information Sheet

ACORN-II

We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with partner, friends and relatives if you wish.
- You are free to decide whether or not to take part in this trial. If you choose not to take part, this will not affect the care you get from your own doctors.
- Ask us if there is anything that is not clear or if you would like more information.

Important things you should know

- We want to find out whether or not our CALM intervention is more effective in reducing antenatal anxiety than treatment as usual for women/birthing persons.
- CALM has been shown to be effective in a smaller study before now.
- There is a 50% change that women/birthing persons may get treatment as usual.
- You are being asked to take part of the trial as you are either the partner or close supporter of a pregnant woman who has been approached.
- The trial involves a total of four where we will ask you to complete questionnaires over a period of 18 months (before the intervention; at 22-weeks pregnant; 32 weeks pregnant and 12 months after giving birth).
- You can stop taking part in the study at any time.

Contents

Why are we doing this study?

- Up to 25% of women struggle with serious anxiety symptoms during pregnancy.
- Antenatal anxiety is associated with negative outcomes in couple relationship and child outcomes.
- When a woman has a partner/close supporter they often share in their pregnancy experience and research has shown that partners/close supporters want to be involved and equipped with the tools to help support the mother.
- There have been very few studies which have tested interventions that have successfully included partners/close supporters.

Why have I been invited?

- We are approaching all pregnant women/birthing persons aged 18 and above at their first trimester scanning appointment to be screened for anxiety and their partners/close supporters.
- If the woman/birthing person is eligible, you, as their partner/close supporter, will be invited to take part in the trial as well.

What do we want to find out?

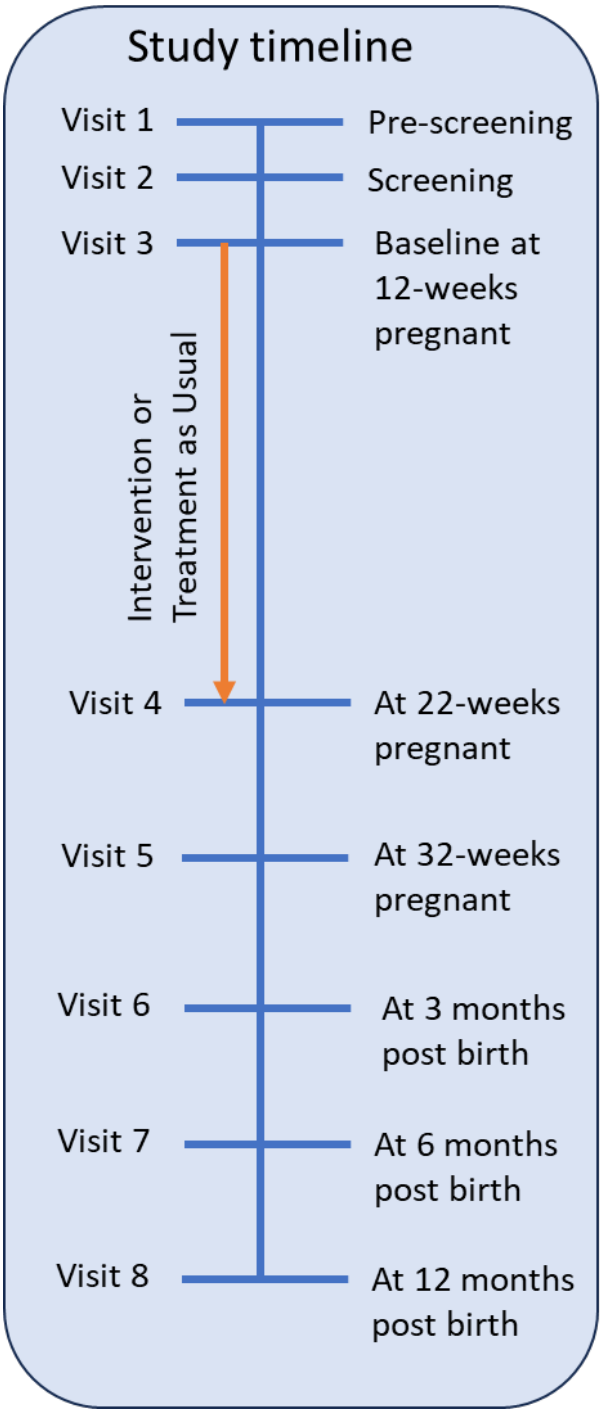
- In a previous feasibility study we developed and tested an intervention called CALM with a smaller number of pregnant individuals with anxiety and their partners/close supporters.
- CALM reduced their anxiety.
- We now want to do a bigger trial to see whether CALM improves anxiety in pregnant individuals during pregnancy and has effects on the relationship with partners and babies.

What is the CALM intervention?

- 5-session group-based therapy delivered to pregnant individuals and their partners/close supporters alongside Treatment as Usual over a 5-week period.
- CALM uses evidence-based cognitive-behavioural and mindfulness strategies to address worry and pregnancy-specific uncertainties.
- It was co-produced with individuals who had experienced anxiety during their pregnancy and their partners/close supporters.
- The intervention is delivered by a psychological worker and a maternity worker (e.g. midwife).
- Sessions can be done remotely or in person.
- There will be around 8 pregnant individuals in each group and their partners/close supporters (maximum of 16 in a group).

What is the Treatment as Usual (TAU)?

- TAU is either:
    - Support from a specialist mental health midwife, or;
    - A referral to general Cognitive Behavioural Therapy in Talking Therapies services through a midwife or GP.



What happens if I take part?

Contact 1 – Pre-screening

- A researcher will approach you from the trial team about the trial at the first trimester scan appointment.
- If you are happy to take part you will be asked to complete a consent to contact form
- This will take you 5 minutes to complete
- Once we determine whether or not the pregnant woman/birthing person is eligible we will contact you.

Contact 2 – Baseline

- The baseline visit will take up to 1 hour
- A researcher will contact you to talk through the study and answer any questions you have about the trial.
- If you are happy to proceed you will be asked to complete a consent form
- You will be asked to complete some questionnaires either online or over the phone with a researcher which will help us understand how you are feeling

Contact 4,5 – Follow up

- If you were assigned to the intervention group you would have completed the sessions by visit 5.
- For the follow up visits you will be asked to complete questionnaires around your mood either online or over the phone with a researcher
- A link to your personalised questionnaires will be sent to you over email.
- These visits will take around 40 minutes.

Contact 6 – Final visit

- The final visit will take up to 1 hour.
- You will be asked to complete questionnaires around your mood either online or with a researcher.
- You will also be asked to be recorded interacting with your baby. We are doing this to look at whether the intervention improves the relationship you have with your baby. The visit can be done in person or remotely through a video call.

What are the advantages in taking part?

- 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 and has an impact on relationships.

What are the risks in taking part?

- 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.

Who has reviewed the study?

The study has been reviewed and approved by the National Research Ethics Service (NRES) Committee [INSERT ETHICS COMMITTEE]. It is sponsored by Devon Partnership Trust and funded by the National Institute of Health Research.

What will happen to the results?

The findings of the study, and anonymised quotes will be published in academic journals, funding reports and presented at research meetings and conferences. However, your name will not be used in any written or verbal reports arising from the research. If you are interested in obtaining a summary of the results, or a copy of any publication(s), please let the study researcher know, and we can arrange to send a copy to you when the summary and/or other publication(s) are available.

Who can I contact for independent research information?

If you have any questions about being in a research study, you can contact the Trust's Patient Advice Liaison Service (PALS). They will give you advice about who you can talk to for independent advice.

What if I want to withdraw?

- Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your care being affected.
- If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Will I get paid for participating?

You will not be paid during the course of the study for any travel expenses if the intervention sessions take place in person.

Who can I contact for further information about taking part?

You can contact a member of the research team locally:
[Site researcher name] on [Site researcher telephone:] or email them on [Site researcher telephone email]

You can also contact the trial manager Antoinette Davey on [telephone number] or email her on Antoinette.davey@nhs.net

What if something goes wrong?

If you wish to complain, or if you have any concerns about any aspect of the way you have been approached or treated during the course of the ACORN-II trial, by University of Exeter, University of Cambridge, University of Birmingham, Manchester University, or by NHS employees, the normal complaints mechanisms will be available to you.

If you have specific concerns or questions about the study, you can contact the study researcher (see contact details below) or the Chief Investigator at the University of Exeter (Professor Heather O'Mahen – telephone: 01392 724651 or e-mail: H.OMahen@exeter.ac.uk).

What if I want to complain?

If you are not happy with the way you have been treated by an NHS service, you have the right to complain, have your complaint investigated, and be given a full and prompt reply. You can ask the organisation (e.g. GP practice, hospital or NHS Trust) for a copy of its complaints procedure, which will explain how to make a complaint. Your first step will normally be to write or speak to the health professional (e.g. the nurse or doctor) concerned, or to the complaints manager within their organisation. Alternatively, you can contact the relevant commissioning body such as the NHS England or a local Clinical Commissioning Group (CCG). You may also wish to seek advice from your local Patient Advice and Liaison Service (PALS) – all hospitals have a PALS Officer. More information about the NHS Complaints Procedure can be found on the NHS Choices website at: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx

Terms explained

Antenatal

- The period of time during pregnancy.

Postnatal

- The period of time after the baby is born, post pregnancy.

Anxiety

- It is a feeling of fear, worry, and uneasiness.

Feasibility study

- A study to evaluate whether or not a project plan could be successfully carried out testing an intervention.

Randomisation

- Randomisation means that a group of people are split into two groups at random; one group is given one intervention (CALM) and the other is given a different intervention (treatment as usual).
- For this trial, we will measure how each group is doing and see if one group has achieved its supposed outcome any better.

Trial Intervention

- A trial intervention is designed to answer specific questions about the intervention.
- The trial intervention is defined as a treatment for a specific condition.
- The purpose of a trial is to see whether the intervention improves health.

Participant Privacy Information

YOUR RIGHTS

Your usual statutory rights to access, change or move your information are limited, because of exceptions applicable to some types of research, and also because we need to manage your information in specific, lawful ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

CONTACT US

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

How to contact us

If you have any questions about this study, please contact XXXXX (Site researcher) on [email address]

What support is currently available in my area?

[Local support services – NHS and third sector to be inserted for each site]