RAPID 2
Reducing Anxiety in Pregnancy: Intervention Development 2

NHS
Nottingham University Hospitals

The RAPID 2 study. Reducing Anxiety in Pregnancy: A feasibility study of a midwife facilitated supportive intervention for pregnant women with symptoms of mild to moderate anxiety.

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Chief Investigator: Dr Kerry Evans

## Contact details

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## 1. What is the purpose of the study?

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

The RAPID 2 study is testing a way of providing support for women with mild or moderate symptoms of anxiety in pregnancy. The support includes attending online and in-person groups supported by a midwife and using self-help materials. We are conducting this study because research has found that for women with mild to moderate anxiety, this type of support may help improve their wellbeing and prevent anxiety becoming more severe. However, services have not yet been thoroughly tested for pregnant women. A small study was completed in 2017 to help develop the RAPID method of support and women who participated felt they had benefitted.

To help us develop this method of support, we are conducting a feasibility trial. This means we would like to find out if women are interested in taking part, their experiences of taking part, and find out the best ways of measuring the effects of the support. Sometimes we don't know which method of support is the best. To find out, we need to make comparisons between different methods. We put people into groups and give each group a different method of support; the results are compared to see if one is better. To try and make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The results are then compared. For this study we are comparing groups which will receive the RAPID support and usual maternity care, with groups which will receive usual maternity care. Women in both groups will be able to access all their usual care and support services available to

them in their area throughout the study period - it is important you know that your usual maternity care will not be affected in any way if you take part in the study.

## 2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, East Midlands - Derby Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute for Health Research will fund this research.

## 3. Why have I been asked to take part?

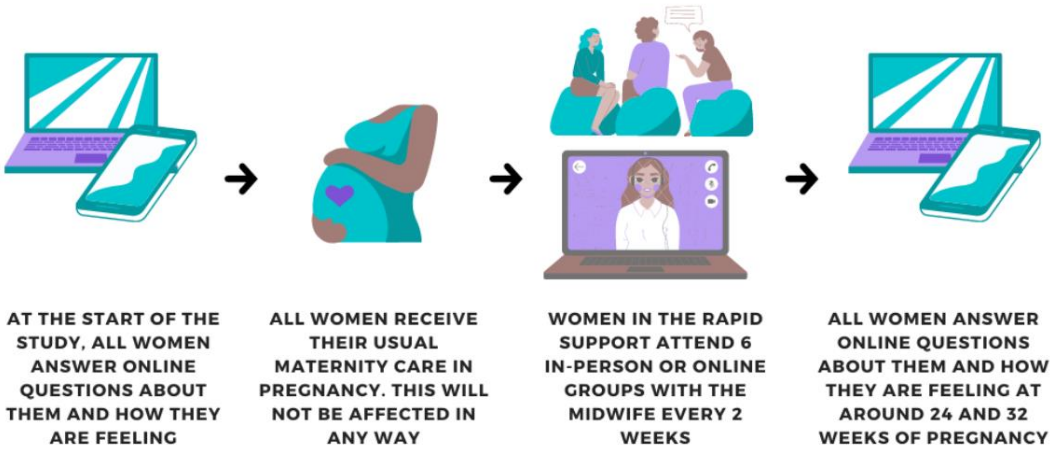
We want to include you in this study because you have told us that you are having your first baby and your replies to the study page questions indicated that the support we are developing may be suited to your needs. That means your views and experiences would be important to us.

**Do I have to take part in this study?**

No. It is up to you to decide whether or not to take part. If you decide to take part, you can access or download this information sheet to keep and will be asked to complete a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

If you withdraw, we will still keep your data up until the point of withdrawal, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

## 4. What do I have to do?




**What will happen to women that are allocated to receive the RAPID method of support?**

You will be asked to answer some questionnaires about how you are feeling, the types of support you have around you and about your living and employment situation. If you are happy to take part, the researcher will contact you using your chosen method of contact and you can ask any questions. You will then be invited to meet the RAPID midwife to talk about the groups and ask any further questions.

You will then be invited to attend groups, one per fortnight over 12 weeks. There will be at most ten women in the group. You will also be provided with self-help materials which you can use between groups. Groups will be held online or in community healthcare centres and you will be able to speak one-to-one with a midwife if you wish. Groups will be audio recorded so we can find out how they were run in the different areas but nothing which can identify you will be reported.

Mid-way through and at the end of the study we will ask you to complete the same questionnaires again. We will ask some women to take part in an interview to ask about their experiences. The interview will last for approximately 60 minutes and will be audio recorded but nothing that could identify you as an individual will be discussed outside the research team. When we write the report, we might use direct quotes from the interviews, but we will ensure that any quotes we use will not identify you as an individual. Your involvement in the study will last for around 18 weeks in total.

**What will happen to women that are not allocated to the RAPID method of support?**

You will be asked to answer some questionnaires about how you are feeling, the types of support you have around you and about your living and employment situation. Mid-way through and at the end of the study we will ask you to complete the questionnaires again. When we write up the findings, we will

not report anything that can identify you as an individual and your name will not be used. Your involvement in the study will last for around 18 weeks in total.

## 5. What are the possible benefits?

We cannot promise the study will help you but the information we get from this study may help other women in the future.

## 6. What are the disadvantages?

We think that it is unlikely that there will be any drawbacks in taking part, although women may sometimes feel upset when discussing their feelings. We ask that for women participating in groups, you only share something that you are comfortable to share. The midwife leading the group will be available to discuss any concerns with you.

## 7. What will happen to my data?

All the information about your participation in this study will be kept confidential. We will keep all information about you safe and secure. If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper, and electronically at the main hospital site managing this research under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms. If you are randomised to the intervention group, your name and contact details will be passed to the midwives and midwifery support workers who will be delivering the intervention, in order to facilitate this. Other group members will also become aware of who you are when you attend the group sessions however, they will only know any information about you, which you share during these sessions.

If you withdraw consent from the study at any time, your data up until the point of withdrawal, will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

With your permission your GP (and other doctors who may be treating you) and your midwife may be notified that you are taking part in this study. The information collected about you may be shown to authorised people from the sponsor to ensure that the study is carried out correctly. All will have a duty of confidentiality to you as a research participant. We will need to use information from you for this research project. This information will include your initials / NHS number / name / contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

If any information is revealed during the study which could indicate a risk of serious harm to yourself or others, the research team have a duty of care to report this information to your healthcare providers and the Chief Investigator. If this situation arises, the midwives and the Chief Investigator will discuss this with you and you will be fully informed of any intended actions.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your information by asking one of the research team, by visiting www.hra.nhs.uk/information-about-patients/ or by visiting www.nuh.nhs.uk/gdpr

## 8. What will happen if I don't want to carry on with the study?

If you don't want to carry on with the study, you can choose to withdraw on the study webpage or by speaking to the researchers. We will still keep records of your data up until the point of withdrawal as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive. If you have not told us that you no longer wish to participate and do not attend the groups or complete questionnaires, the researcher will attempt to contact you using

the contact information you provided. The researcher will discuss any concerns or ask if you wish to continue or withdraw from the study. We will make no more than two attempts contact you.

## 9. What happens when the study is finished?

Information may be published in a report for the funder and in peer reviewed academic journals; presented at professional conferences or local seminars. Should you wish to see a summary of the study report please ask the researcher to forward a copy to you.

## 10. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact the Patient Advice and Liaison Service (PALS) telephone 0800 183 0204.

In the event that something does go wrong, and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

## 11. Further Information

You are encouraged to ask any questions you wish before, during or after the study. If you have any questions about the study, please speak to the researchers of the study midwives who will be able to provide you with up-to-date information about the study and what is involved. If you require any further information or have any concerns while taking part in the study, please contact the lead researcher (listed at the top of this document).

If you decide you would like to take part, then please read and complete the consent form. You can download or access a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed with the study records.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.