

Women's and Professional's Experiences and View of Current Fetal Monitoring and Continuous Fetal Monitoring

Participant Information Sheet (PIS)

Thank you for considering taking part in this research study to explore your **experiences and views on current fetal monitoring methods and continuous fetal monitoring**. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, contact a member of the research team.

About the research

➤ Who will conduct the research?

Miss Eleanor Godhard, MRes Reproduction and Pregnancy Student, Maternal and Fetal Health Research Centre, The University of Manchester

This study is for the certification of an MRes degree from The University of Manchester.

Professor Alexander Heazell, Professor of Obstetrics, Maternal and Fetal Health Research Centre, The University of Manchester

This study has been reviewed by The University of Manchester UREC 2.



➤ What is the purpose of the research?

Monitoring of a baby's well-being in the womb is commonplace in modern pregnancy care, often using ultrasound, Doppler Velocimetry and Cardiotocography (CTG). These devices only provide **a snapshot** of a baby's well-being, and therefore new technologies are being developed that can monitor a baby in the womb over a long period of time (**Continuous fetal monitoring**).

We are doing this research project to explore women's experiences of fetal monitoring techniques, and their views on continuous fetal monitoring, to see what is important to women in terms of wearability of a device, and how fetal monitoring impacts them. Professional's experiences and views of continuous fetal monitoring will also be explored to assess acceptability of new devices into their clinical practice, to shape future care. This will be conducted through an online focus group.

This study will enable improvements to new devices to be made, to make them more acceptable to women who will be wearing them. Also, to identify any potential barriers clinicians may have in using such devices, with an overall aim to improve fetal monitoring to ultimately reduce adverse perinatal outcomes.

➤ Am I suitable to take part?

- Professional's (Obstetricians or midwives) who have experience using fetal monitoring devices in the UK.
- Ultrasound, Doppler Ultrasound, CTG for example.
- Participants will be invited via social media channels.
- It is required that you have access to a **computer, tablet or mobile phone with video and a stable internet connection** (for the Zoom focus group)

➤ Will the outcomes of the research be published?

It is anticipated that this research shall be made public (Published). The results will also be published in a research team member's Masters dissertation. All collected data will be anonymised prior to publishing.

➤ Who has reviewed the research project?

This project has been reviewed by The University of Manchester Research Ethics Committee 2.

What would my involvement be?

➤ What would I be asked to do if I took part?

You will be invited to attend an online focus group, via zoom. The following dates are provisional options for the focus groups, you will be invited to attend one, depending on the availability of participants:

- **Monday 16th May 2022: 15:00pm-16:30pm/17:30pm-18:00pm/20:00pm-21:00pm**
- **Tuesday 17th May 2022: 09:30am-11:00am**
- **Wednesday 18th May 2022: 16:00pm-17:30pm/20:00pm-21:00pm**
- **Wednesday 25th May 2022: 10:00am-11:30am/17:00pm-18:30pm/20:00pm-21:00pm**

Firstly, each member of the focus group will be asked to introduce themselves and briefly describe their experiences. The chair of the focus group will then guide an open discussion through some pre-defined topics. We would like to hear your experiences and opinions so please share anything you believe to be relevant to this study. We ask that each participant respects each member of the focus group, in terms of confidentiality and letting each member have their say.

The focus groups will be audio recorded and anonymised when transcribed. By taking part participants are consenting to their responses being used in this research project to improve the use of current devices and future devices for fetal monitoring.

The focus groups will last between 60-90 minutes.

Some participants may share a distressing experience and evoke negative emotions. Please remember that your participation in the focus groups is **completely voluntary** and you may leave at any time.

There may be instances where during the research where information is revealed which means the researchers will have to breach confidentiality. For example, safeguarding concerns or malpractice, the researchers will then be obligated to inform the relevant bodies.

Once anonymised and transcribed, the responses will be reviewed and analysed and available to the research team at the Maternal and Fetal Research Centre, The University of Manchester.

Any future care or work will not be influenced by your participation in the focus groups. The medical team and or Healthcare trust will not know whether an individual has attended the focus group and what has been said.

➤ What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are **still free to withdraw at any time without giving a reason and without detriment to yourself**. Please contact the research team if you wish to withdraw prior to the focus group.

Participants are free to leave the focus group zoom call at any time. However, participants may be contacted for welfare checks if they leave the focus group in distress.

It will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights.

If you decide not to take part, you do not need to do anything further.

As it is essential for the focus groups to be audio-recorded, participants are unable to decline to be recorded if they wish to participate. Participants must be comfortable with audio-recording happening throughout the focus group.

Will I be compensated for taking part?

For your time and as thanks for your participation in the focus group, you will be compensated £50 (NIHR INVOLVE). Following completion of the focus group, participants will be paid through the University of Manchester non-university/ external personnel Fee Claim Form (PR7). The information will be stored directly with the University Finance and Fee department. This form will be emailed to participants to fill out and sent to feesandexpenses@manchester.ac.uk



Date: 25/04/2022

Data Protection and Confidentiality

➤ What information will you collect about me?

In order to participate in this research project, we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect:

- **Name**
- **Contact details (email)**
- **Record of Consent**

In order to compensate you for your time, The University of Manchester will need to collect your bank details through the Fee expenses form.

The audio-recording will include:

- **Voice only**
- The focus group will take place on zoom, however only the audio shall be recorded, not the participants face/surrounding environment

➤ Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ What are my rights in relation to the information you will collect about me?

You have **several rights** under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings.

The information which we collect will ultimately be anonymised, and therefore unidentifiable.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#).



➤ Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential, and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- Only the study team at the University of Manchester will have access to the focus group recording and anonymised transcript.
- To ensure confidentiality, participants will be anonymised following transcription of the focus groups audio.
- The identifiable focus group audio-recording will be kept in a secure electronic location.
- The anonymised focus group transcripts will be kept in a secure electronic location.
- The anonymised transcripts shall be transcribed by a member of the research team.
- By participating in the focus group, you are consenting to your anonymised transcript to be used in our research.
- Data will be stored for 5 years.
- Audio-recording will be deleted following transcription.

Your participation in this research will be recorded in **Zoom and your personal data will be processed by Zoom**. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. **The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.**

The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed. Your consent form will be retained for 5 years in a locked cabinet on UoM premises for audit purposes.

➤ **Potential disclosures**

If, during the study, we have concerns about your safety or the safety of others, we will be obligated to inform the relevant bodies.

If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this and will therefore need to inform your employer/professional body.

If, during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

If you would like more general information on how researchers use data about patients, please visit: : www.hra.nhs.uk/information-about-patients/



➤ **Harm:**

In the unlikely event that something does go wrong, and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What if I have a complaint?

➤ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact:

ALEXANDER HEAZELL – PROFESSOR OF OBSTETRICS

Alexander.heazell@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL

research.complaints@manchester.ac.uk

0161 306 8089.

If you wish to contact us about your data protection rights, please email: dataprotection@manchester.ac.uk

The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](#) Tel 0303 123 1113

Contact Details

If you have any queries about the study or **if you are interested in taking part**, then please contact the researcher:

ELEANOR GODHARD – MRes Student

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