

CAL-Obs Study

We are inviting you to take part in a research study called: Computer Assisted Quantification of Learning Curves in Obstetric Ultrasound and Invasive Procedures, “CAL-Obs”

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you receive in any way.
- You can stop taking part in the study at any time, without giving a reason.
- Ask us if there is anything that is not clear, if you would like more information or if you need any special assistance.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and asked to sign a consent form. You will get a copy of that as well.

Important things that you need to know

- Healthcare workers spend time training to learn how to do ultrasound scans. We want to find out how performance of a less experienced operator differs from an experienced one.
- Your sonographer will wear ‘eye-tracking’ glasses and we have added a motion sensor to the ultrasound scanner. This equipment will allow us to record how hand-eye coordination differs between the groups.
- The study fits into your normal treatment, so there are no extra hospital visits. Your sonographer will perform exactly the same scan as they otherwise would.
- This study forms part of a PhD Thesis.
- We will retain an anonymised version of your ultrasound, this means that nothing we keep can be used to identify you.

1 Why are we doing this study?

We want to find out how healthcare practitioners move when they do ultrasound scans. During your ultrasound all of the less experienced operators will be carefully supervised by an experienced operator, just as they would be if you were not participating in this study.

During the scan you may notice that the person performing your scan is wearing glasses. These record the operators eye movements during the scan and what the operator is looking at. The ultrasound transducer or ‘probe’ will also have an attachment which records the position of the transducer during the scan.

The purpose of this study is to examine how the hand and eye movements of a less experienced operator differ from an experienced one. We believe that if we can identify the differences between expert and novice operators then we can improve training and education. We believe that this will contribute to better patient care.

Our aim is to develop a device which can help novice operators to get the best quality image and scan information possible, while the scan is in progress. To develop this we need ultrasound data paired with eye and hand movements. These data have never been collected before and we would like to use the information collected during your scan for this project.



Figure 1 – Eye Tracking Glasses worn by the operator

2 Why am I being asked to take part?

You are being asked to take part in the CAL-Ob's study you have been invited to attend hospital for a routine detailed "anomaly" scan of your baby in the middle of pregnancy. We believe that we may be able to improve training, shorten the time it takes to train people to perform this scan independently and to improve the quality of the scan. There is a lack of reliable evidence as previous studies were not specifically designed to answer whether computer assistance could help novice ultrasound operators or not.

3 What do I need to know about the procedures in this study?

Every pregnant woman is offered a detailed scan of her pregnancy between 18 and 21 weeks. The purpose of the scan is to screen for structural abnormalities with your baby. The clinical information gathered and any follow-up, should it be required, will not differ in any way from women who are not taking part in the study.

This study uses an Electromagnetic Field Generator to track the position of the ultrasound probe during the scan. Electromagnetic Fields are not known to be harmful in early or late pregnancy. Electromagnetic fields are generated by a moving electric current. Electricity cables, computers and mobile phones all generate electromagnetic fields. Wi-Fi and Bluetooth are examples of electromagnetic fields used in daily life. The World Health Organisation (WHO) has concluded that exposure to everyday electromagnetic fields does not constitute a health risk. If you are concerned, please ask a member of study staff.



Figure 2 – Experimental set-up of the Ultrasound Probe Tracker and the eye tracking glasses using a model abdomen.

What are the most common side-effects?

Any medical treatment could have unwanted side-effects. There are no known side effects from ultrasound in pregnancy.

4 What will I need to do if I take part?

There will be two different groups in this study. These are:

- women scanned by a less experienced operator
- women scanned by a more experienced operator

Everyone who takes part will be in one of these groups.

Which group will I be in?

It is important that the groups being scanned are as similar as possible at the start of the study. You will have an equal chance of being allocated to either group. This ensures that the groups being compared in the study are as similar as possible to start with and that any differences between these groups are only due to the operator, rather than the pregnancies being scanned.

What will happen to me during the study?

When you enter the scan room the operator will explain what will happen during the scan and take verbal consent to perform the scan, as they would do for every scan. You will already have signed a consent form to take part in the study and this will be checked by a member of the study team.

The scan won't differ from the scan performed on women who are not taking part. The operator will wear glasses and you will notice a small white box in the area around the scan couch. This box tracks the ultrasound probe throughout the scan.

Once the operator has completed the scan you will be free to leave the department.

5 What are the possible benefits of taking part in this study?

We do not expect the study to be helpful to you in this pregnancy. The information that we collect will help us to decide if the device that we are developing is effective and could be used to improve training in obstetric ultrasound, invasive procedures like Amniocentesis and, in the future, Fetal Surgery.

6 More information about taking part

Do I have to take part in the CAL-Obs study?

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form.

A decision to not take part at any time will not affect the standard of care you receive.

Can I stop taking part after I've joined the study?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. Before you withdraw from the study a member of the research team can advise you about any concerns you may have.

If you stop taking part in this study, you will receive standard pregnancy care. A decision to stop taking part at any time will not affect the standard of care you receive.

What will happen to the results of the study?

Following this study, the findings will be presented to staff within this hospital.

The aim will be to submit the findings in the form of an abstract to a fetal medicine conference and publish the findings as a research paper in a medical journal.

Results will be included as part of the PhD thesis of the Student Researcher.

Who is organising and funding the study?

This study is sponsored by University College London (UCL). The study has been reviewed by the UCL Ethics Research Committee, reference number 18/094 and NHS Ethics Research Committee, REC 19/HRA/3411.

7 How will we protect and use your data?

UCL is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific 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.

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.

We use personally-identifiable information to conduct research to improve health and care. As a University we have a legitimate interest in using information relating to your health and care for research studies, when you agree to take part in a research study. This means that we will use your data, collected in the course of a research study, in the ways needed to conduct and analyse the research study. Your rights to access, change or move your information are limited, as we need to manage your information in specific 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.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. 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).

Our Data Protection Officer is Lee Shailer and you can contact them at data-protection@ucl.ac.uk.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

What if I have further questions, or something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with Dr Brian Dromey who will do their best to answer your questions. If you remain unhappy and wish to complain formally about any aspect of the way you have been approached or treated during the course of this study, you may contact the Chief Investigator Prof. Donald Peebles who will forward your complaint to the Sponsor's office. In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against UCL but you may have to pay your legal costs.

8 Contacts for further information

Thank you for taking the time to consider taking part in this study, if you have any questions about this study, please contact our research team. You can find out more about how we use your information by contacting;

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