<Add local headed letterhead>

Postnatal
Participant Information Sheet

Rotation of the fetal head at full cervical dilatation (ROTATE)

Randomised controlled trial of manual versus instrumental rotation of the fetal head in malposition at birth

Version 3.0 27th April 2022

1. Invitation

You have previously been invited to take part in the ROTATE research project. **You have decided to take part in the study and if you have since decided you no longer want to take part you will still receive standard NHS care.** As you have provided verbal consent, we would like to remind you why the research is being done and what it will involve for you now your baby has been born. A member of our research team will go through this information sheet with you and answer any questions you may have.

This Participant Information Sheet (PIS) tells you the purpose of the study, what will happen now you are taking part, and detailed information about the conduct of the study. Please do take the opportunity to ask any questions you have.

2. What is the purpose of this study?

The ROTATE study is investigating how best to get babies into a good position for a vaginal birth when problems arise at the end of labour.

At this stage, when the mother's cervix is fully open, most babies have rotated round in their mother's pelvis so that the back of their head (the occiput) is at the front of the pelvis. This position is most likely to result in a straightforward vaginal birth. But some babies end up in a position where the back of their head is against mum's spine, or her left or right hip, making it more difficult for mum to push her baby out and more likely for her to end up with bad tears and/or an emergency caesarean birth. You may

have heard this position referred to as ‘back to back’, ‘stars looking’ or ‘malposition’.

In this situation an obstetrician (a doctor specialising in pregnancy and birth) will help turn the baby so their head is in the best position for birth. They have two options:

1. Using their hands to rotate the baby (manual rotation). The mum may then be able to push her baby out without further assistance. If not, the obstetrician will use forceps or ventouse to help birth the baby.
2. Using forceps or ventouse to rotate the baby (instrumental rotation) and then to help birth the baby.

Giving birth using either of these techniques is known as an operative vaginal birth.

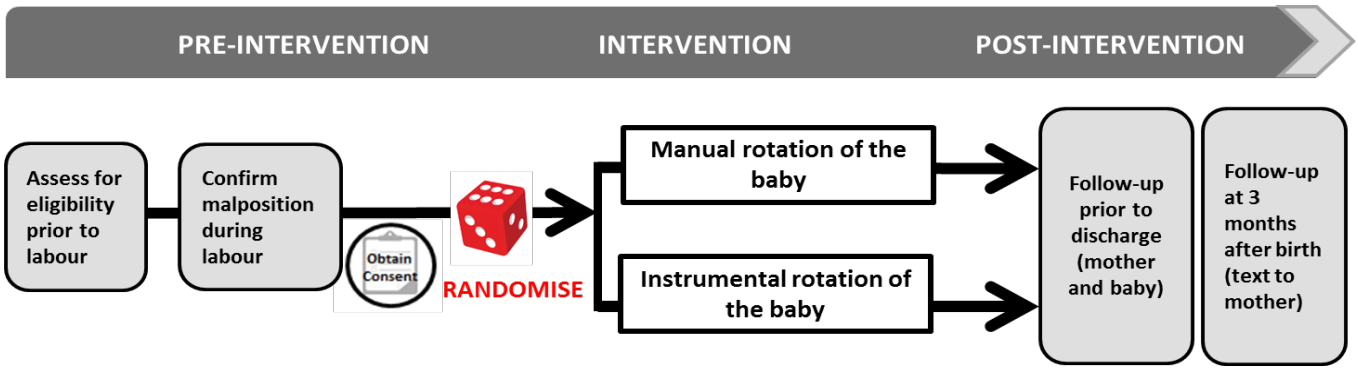
Currently, there is no conclusive evidence to say which method of rotating the baby’s head is best. Different doctors do different things, and that is why we are doing the ROTATE study.

We want to find out which of these two methods is the best for both mothers and their babies. We will be collecting information about the outcomes, such as tears and late caesarean sections. Obstetricians generally want to avoid carrying out caesareans in the second stage of labour as they are riskier to mum and baby than those that take place before labour starts or in early labour.

3. Why was I asked to take part?

You were invited to take part because your baby was in a difficult position at the end of your labour and assistance from an obstetrician was needed to rotate your baby into a better position for birth.

4. What does taking part involve?



As you decided to take part in the ROTATE study, you provided verbal consent to your midwife or obstetrician during labour that you were happy to take part in the study.

Details about you and your pregnancy were then put into a computer which randomly picked for you one of two methods of rotation:

- **Manual rotation**
- **Instrumental rotation**

Your midwives and doctors discussed with you the details of having an operative vaginal delivery, and the benefits and risks associated with this type of birth.

Neither you nor your health care team decided which rotation group you were in. All other aspects of your care were the same as if you decided that you did not want to take part in the ROTATE study. Your health care team may have changed your allocated method of rotational delivery if they thought that there was a clinical need for you to give birth differently.

Now that you have given birth, your consent is now being confirmed in writing. This form records your agreement to take part in the remainder of the study and to have information about you and your baby shared confidentially with the research team at the University of Birmingham who are running the study.

The consent form must be signed, either by you in person, or by you in discussion with research staff by phone or video (in which case you will then send the consent back to the hospital). Should you choose not to give written consent, we will only keep the anonymous information already collected and you will not be expected to participate further.

Most of the information that is needed about you and your baby will be collected directly from your medical notes and data routinely collected on NHS and central government databases.

Before you leave hospital, you will be asked to complete three questionnaires about:

- Your experience of childbirth
- Feeding your baby
- Any issues with incontinence

If you are unable to complete these questionnaires before leaving hospital, this can be posted back to the research team or completed with the assistance of the research midwife, either over the phone or face-to-face at a postnatal visit. We will link your responses with other data through your study number, so your identity remains confidential. There are also 5 questionnaires to complete approximately 3 months after the birth of your baby.

The answers that you provide will help health care staff and researchers get a fuller picture of your birth and postnatal experiences. Also, we will ask for your permission to link your and your baby's health records with other routinely collected health, educational, or social data, to learn more about the short and long term impact of the different rotational methods.

Finally, the consent form will also ask for your permission to be contacted in the future if we wish to collect more information about how you are and how your child is developing. By giving your permission to be contacted in the future, you are not committing yourself to taking part in a new follow-up study.

5. What were the possible benefits of taking part?

We currently do not know which method of rotation, if either, will have more benefits for the woman and her baby.

It is possible that you and your baby have not gained any personal benefit from taking part in the ROTATE study. However, your participation in the trial will provide valuable information to decide which method minimises the risk that women (and their babies) may experience in the future.

6. What were the possible disadvantages and risks of taking part?

One of the methods could be associated with increased risk to you and your baby, however we do not know at present which is the best method.

Please be assured that your clinical team worked in the best interests of you and your baby.

7. Who is organising and funding the research?

The ROTATE study is being funded by the National Institute for Health Research (Ref: NIHR127818).

The study is being sponsored by University College London (UCL) and managed by the University of Birmingham Clinical Trials Unit.

No one involved in the trial is being paid to recruit women into the study and women are not paid to take part either.

8. How have patients and the public been involved in this study?

The design of the ROTATE study has been guided by a survey of women with experience of operative vaginal birth. The Birth Trauma Association and the National Childbirth Trust also took part in developing the research. We have patient representatives on the Trial Management Group and a Trial Steering Committee that oversee the project. These representatives inform all aspects of the trial, including study design, materials, and procedures.

9. Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee (REC) to protect your safety, rights, well-being and dignity. This study has been approved by the London - Surrey Research Ethics Committee and the Research & Development (R&D) department at this hospital.

10. Will my taking part in this study be kept confidential?

Yes - all information collected in the study will remain strictly confidential in the same way as your other medical records.

11. How will we use information about you?

With your permission, we will use information from your medical records and those of your baby for this research project. University College London (UCL) will be using this information to undertake the study and will act as the data managers. This information will include your:

- NHS number
- Name
- Contact details

UCL are responsible for looking after your information, using it appropriately and keeping identifiable information about you for 25 years after the study has finished.

If you agree to take part, you will be assigned a unique study number. The answers you give will be linked to this study number and not your name. In routine communication between your hospital and the ROTATE Trial Office, you will only be identified by your study number, last four digits of your NHS number and your month and year of birth. All individuals who have access to your information have a duty of confidentiality to you.

[*NHS/other site*] will collect information from [*you and/or your medical records*] for this research study in accordance with instructions from the trial team. [*NHS site*] will use your name, NHS number and contact details (including email address, telephone number) to contact you, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. [*NHS site*] will pass these details to UCL and the University of Birmingham along with the information collected from you and your baby's medical records. Individuals from UCL, the University of Birmingham and regulatory organisations may look at your medical and research records to check the accuracy of the research study and to check your records to make sure that the research is being carried out properly. The only people who will have access to information that identifies you are those who need to contact you to answer any questions about your or your baby's participation in the ROTATE study or to audit data collection. People who do not need to know who you are will not be able to see your name or contact details, only your unique study number. The people who analyse the information will not be able to identify you. Everyone involved in this study will keep all information about you safe and secure. We will also follow all privacy rules.

We would like your permission to keep the information we have collected about you and your baby, as we may be interested in this information to assess your long-term health and that of your child. It would be used to link-up the ROTATE trial data with routinely-collected health, educational, or social data stored at central UK NHS bodies, such as NHS Digital, without contacting you further. To do this linking-up, we will send the central NHS bodies your and your baby's NHS number, date of birth, and sex; these central bodies will link your details to their data and send this information back to the ROTATE study team. If we need further information that is not in the routinely collected information at NHS Digital, we would like permission to recontact you to find out if anything related to the birth has affected other health outcomes. Also, we would contact your child when s/he is 16 years of age to ensure that they are happy to continue having their information used in our research.

Your date of birth was shared with The Centre for Healthcare Randomised Trials (CHaRT), so they could assign a trial intervention. CHaRT will not use this data for any other purpose.

From time to time, we may be asked to share the data we have collected with researchers running other studies so that they can answer other important research questions. These studies may be at universities, NHS organisations or companies involved in health research and may be in this country or abroad. Any such request to share information will only be granted if the necessary procedures and approvals are in place. This information will not identify you or your baby and will only be used for the purpose of health research. It cannot be used to contact you or affect your care.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our records in a way that no-one can work out that you took part in the study.

12. What are your choices about how your information is used?

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways so that the research is reliable and accurate. This means that we won`t be able to let you see or change the data we hold about you. You can, however, withdraw from the study at any time, without giving a reason. Please see section 16 of this information sheet for further details.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information at UCL here:
(https://www.ucl.ac.uk/research/integrity/)

or

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to ROTATE@trials.bham.ac.uk
- by sending an email to data-protection@ucl.ac.uk

The data custodian for this study is Professor Dimitrios Siassakos, ROTATE Chief Investigator.

14. Involvement of General Practitioner

Your general practitioner (GP) or other health care professional(s) **will not** be informed of your participation in the trial. You are more than welcome to inform your GP or other health care professional(s) of your participation in trial if you wish to do so.

15. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Patients Advice and Liaison Service (PALS). Contact information for your local researcher and PALS service can be found at the end of this patient information sheet.

The Sponsor (UCL) has in place Clinical Trials Indemnity coverage for this study. If you are harmed by taking part in this research study, UCL will be liable if harm was due to the research and not the underlying clinical care. In the event that something does go wrong and you or your baby are harmed during the birth due to someone`s negligence you may have grounds for legal action for compensation. The normal NHS complaints processes will still be available to you (if appropriate).

16. What if I change my mind and no longer want to take part?

You are free to withdraw from the study at any time and you do not have to give a reason why you have changed your mind. Deciding to withdraw from the study will not change the standard of care received by you or your baby.

If you choose to withdraw, then upon request, all stored data collected thus far *will not* be processed, and no additional participation would take place.

In the unlikely event that you lose the capacity to consent during the study you will be withdrawn, and we will use any data already collected.

17. What happens if new information becomes available?

Sometimes new information becomes available whilst a study is running. If this happens with ROTATE, then a member of the research team will contact you to tell you about this.

If your doctor is happy for you to continue in the ROTATE study, you will decide whether you wish to continue, and you may be asked to re-sign a consent form. If you decide not to carry on in the study, you

will continue to receive normal NHS maternity care.

If your doctor or a member of the research team considers that you should withdraw from the study, then they will explain the reasons why and arrange for your standard clinical care to continue.

18. What happens when the research study stops?

You will receive the same follow-up and care from your hospital health care team and GP as if you had not taken part in this study.

19. What will happen to the results of the research study?

The results of the ROTATE study will be published in medical journals and presented at specialist meetings and conferences. Women who take part in this study will be sent a summary of the findings as well as a link that will allow them to access the results of the trial *via* the trial website. No individual participants or their baby will be identifiable in any results or publications.

20. Do you have any further questions?

Having read this information sheet, we hope you will continue to take part in the ROTATE study. If you have questions about the study now or later, feel free to ask your obstetrician or midwife, or the person at your hospital who is looking after the ROTATE study. Their name and telephone number are at the end of this document.

If you require any general information about research, the UK Clinical Research Collaboration has produced a useful guide entitled, 'Understanding Clinical Trials'. This can be downloaded from their website: www.ukcrn.org.uk. If you require specific information about the research project, please either contact any of the staff listed below or visit our website: https://www.birmingham.ac.uk/research/bctu/trials/womens/rotate/index.aspx. Only the clinical staff looking after you can give you advice.

Thank you for taking the time to read this leaflet about the ROTATE study.

Contact Information

If you would like to speak to someone about the study please contact:

< Contact Name > <Job Title>

<Telephone and/or E-mail>

Support can also be found through *NHS Patient Advisory and Liaison Service (PALS)*

Tel: *<insert local PALS contact number(s)>* Email: *<insert local PALS email address>*