

Would you like to take part in a study about planned caesarean birth?

If you are pregnant with one baby and have chosen to have a caesarean birth at Southmead Maternity Unit, you may be able to take part



Study summary:

- This study is trialing a new method of caesarean birth called “Time-to-Transition”
- “Time-to-Transition” involves a slower caesarean birth, allowing the baby time to start breathing before it is fully delivered
- We propose that this may reduce the chance of babies developing “wet lungs” which can cause breathing difficulty just after birth.
- We will film the births so we can learn from them
- We will collect information about you and your baby, from your medical records
- We will ask you to complete some questionnaires about your birth experience and whether you or your baby have had any extra healthcare in the first month after birth.
- If you have a birth partner, they will also be invited to complete questionnaires about the birth

We would like to invite you to take part in the Time-to-Transition Caesarean Birth Study: A study investigating the feasibility of a 'Time to Transition Caesarean Birth'

Please take time to read the information in this leaflet and discuss it with your friends and family. A member of the research team will be happy to answer any questions you may have.

Why is this study being done?

This is a small-scale “feasibility” study, to help us test how the study will run, and to learn if a larger-scale study would be possible.

This study is testing the Time-to-Transition Caesarean Birth method (explained below), which has been developed by Obstetricians and Neonatologists at Southmead Maternity Unit.

Why have I been invited to take part?

We are offering participation in this study to all women who are:

- having a planned caesarean birth at Southmead Maternity Unit
- pregnant with one baby
- and if the baby is in the “head down” position

Why are you testing a Time-to-Transition Caesarean Birth?

Whilst in the womb, a baby's lungs are filled with fluid, which helps them grow and develop. During labour and birth, most of this fluid goes away, as the baby transitions from life in the womb to breathing air. Some babies might take longer to clear this fluid after they are

born, so the lungs can remain “wet” for longer, making it harder to breathe until the fluid clears. When this happens, babies breathe faster and shallower, a condition known as Transient Tachypnea of the Newborn (TTN) and they often need some additional help with breathing, antibiotics to prevent or clear infection, and sometimes a stay in a Neonatal Intensive Care Unit.

TTN is twice as common in babies born by planned caesarean than those born vaginally, as at caesarean births, babies are typically born very quickly and have less time to clear this fluid and transition to breathing air.

In this world-first study, we aim to assess a new way to perform a planned caesarean to increase the time that babies have to transition: a ‘Time-to-Transition Caesarean Birth’.

What is a Time-to-Transition Caesarean Birth?

Rather than being born rapidly after opening the womb, the doctor will deliver the baby’s head and keep the body inside the womb until the baby starts to cry: a process designed to mimic the transition time which happens in vaginal births. This extra time may help the baby to transition to breathing air and has the potential to reduce the risk of TTN. Reducing “wet lungs” (and TTN) at birth could improve the

experience for many families in the first few weeks after their planned caesarean birth.

What does Time-to-Transition mean for me and my baby?

Most of the preparation and aftercare of you and your baby will be the same as in a routine caesarean birth, but there are some important differences.

The differences are:

1. During the caesarean birth, your doctor will deliver your baby's head and shoulders as normal. Then, instead of immediately birthing the rest of the baby's body, the doctor will wait **up to two minutes** to allow the baby to start breathing or to cry in their own time. The doctor will then deliver the baby's body and continue care in the normal way. This will make birth of the baby more alike a vaginal birth (where the baby's head is typically born with one contraction, and then the body is born up to three minutes later with the next contraction).
2. Your baby's birth will be filmed using two hospital cameras so we can check the method afterwards
3. There may be extra Hospital staff at your baby's birth: a Research Midwife to help with research paperwork and the cameras, and a research Neonatologist to monitor the procedure.

You can still have skin-to-skin and delayed cord clamping if you would like to. As with any caesarean birth, the mother and baby will be closely monitored and if there are any concerns the baby will be

immediately delivered. Everything else about the birth and recovery afterwards will remain unchanged.

What are the potential benefits of taking part?

We don't know if this new method is better than a routine caesarean birth. We hope that the Time-to-Transition birth will reduce the chance your baby will have wet lungs and are less likely to need help breathing, antibiotics, or a stay in NICU. But we can't be sure. This study will help us find out.

For that reason, we don't know if there will be any direct benefit to you or your baby, but you may be helping families in the future once the results of this study are known.

Are there any risks?

We don't expect the Time-to-Transition birth will be riskier to you or your baby. During all caesarean births, including a Time-to-Transition caesarean birth, the mother is monitored closely for blood loss and the baby is monitored for colour, tone, heart rate and breathing. Your baby will be birthed immediately if there are any concerns about you or your baby.

What will the study involve?

We have designed the study to take as little extra time as possible. If you decide you would like to take part, this is what will happen.

The day you have your baby

You will come to Hospital as normal, on the day you are booked to have your baby

You will have all the normal checks before you go to Theatre and your care team will prepare you in the normal way

You will also be asked to confirm you're still happy to have the Time-to-Transition caesarean birth

We will ask you to complete a "Consent to Filming" form so we can film the birth

You (and your birth partner if you have one) will be taken to Theatre where the usual Theatre team will be waiting for you

There may also be a Research Midwife and a Neonatologist present.

The Doctor will deliver the baby using the Time-to-Transition method. You and your baby will be monitored throughout in the normal way.

After the baby is born, you will be cared for in the same way.

The day after your baby is born

A Research Midwife will come to see you on the ward before you go home.

We will ask you to complete a short questionnaire about your baby's birth. It takes about 5 minutes to complete.

We will collect some information about you and your baby from your Hospital record.

A month after your baby is born

We will contact you at home and ask you to complete the questionnaire again.

We will also ask you some questions about whether you or your baby have had any extra care such as GP appointments, or Hospital appointments.

Frequently asked questions:

Q. Can my birth partner be involved?

- A. If you have a birth partner, they can be present at your baby's birth, just as they would if you weren't part of the study. We will ask them for their consent to being filmed during the birth. If they say no, we will film the birth in such a way that they are not visible.

We would also like to invite them to be a part of the **Birth Partner study** which involves them completing the questionnaire about birth experiences after your baby is born. If they say no, you can still be involved in this study.

Q. Can I have a copy of the video?

- A. Yes, if you would like it, you can request a copy. You can still bring your own camera to take your own pictures on the day.

Q. What is the recovery time?

- A. We don't think your recovery time would be any different to if you were having a routine caesarean birth. You will be cared for in the same way after the birth. More information about Caesarean birth and recovery can be found by searching for "Caesarean Birth North Bristol NHS Trust" or by watching this video <https://youtu.be/WEwH5WwMjoE> or by scanning the QR code below



Who is doing this study?

This study is being carried out by staff at North Bristol NHS Trust and the University of the West of England.

How is this study funded?

This study is funded by donations made to the Southmead Hospital Charity.

Who has reviewed this study?

The Health Research Authority and XXX Research Ethics Committee have reviewed and agreed to this study.

What happens next?

- Take some time to read this leaflet and watch our study video and think about whether the Time-to-Transition study is right for you
- A Research Midwife will call you at home to discuss the study and answer your questions
- If you are eligible and interested in learning more, a Research Midwife will talk to you and help you decide if you'd like to take part in this study. If you would like to, they will ask you to complete a consent form
- The following pages of this leaflet contains additional information about taking part in research. Please also consider this when making your decision
- **Remember - taking part is optional - it has to be right for you, your baby, and your birth partner**

Additional Information about taking part in research at Southmead Maternity Unit

The following pages tell you how we will manage information we collect about you, what happens if you change your mind, or if there are any problems.

What if I change my mind?

You can change your mind and withdraw from this study at any time and without giving a reason, but we will keep information about you that we already have. It will not affect the medical care that you receive.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your Hospital and GP medical records. If you do not want this to happen, tell us and we will stop. We will ask you to let us know your preference by completing a study withdrawal form.

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 research data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

How will my information be used?

All research in the UK, which uses patient information must follow UK law (the Data Protection Act) and GDPR* rules.

North Bristol NHS Trust (UK) is the Sponsor for this study. This means we are responsible for looking after your information and using it properly, according to the rules and law.

In this study, we will need to use information from you and your medical records. This information will include your NHS number, name, and contact details. We will use your contact details to get in touch with you by phone, email, or text. We will use your NHS number to access your Hospital and GP medical records to gather information about the health and care of you and your baby. We will use this information to do the research or to check your records to make sure that the research is being done properly. We will write to your GP to let them know you are taking part in the study.

We will keep all information about you safe and secure. People who do not need to know who you are will not need to see your name or contact details. Your data will be given a code number instead. We will write our reports in such a way that no one can work out who took part in the study.

Once we have finished the research study, we will keep some of the data so that we can check the results. We will store study data for up to 5 years after the end of the project, as per standard protocol at North Bristol NHS Trust.

(*GDPR stands for General Data Protection Regulation)

Where can I find out more about how my information will be used?

North Bristol NHS Trust is the sponsor for this study. You can find out more about how we use your information at

www.hra.nhs.uk/information-about-patients. You can also:

- Read our leaflet available from www.nbt.nhs.uk/patientresearchdata
- Ask one of the research team
- Contact Helen Williamson (Head of Information Governance) at helen.e.williamson@nbt.nhs.uk or by calling 0117 4144767

What if there are any problems?

NHS-sponsored research such as this study is covered by NHS indemnity (the same indemnity that applies to any patient in the NHS). In the unlikely event that you feel you have been adversely affected by taking part in this study, you should contact the research team as soon as possible (details at end of leaflet).

Should you wish to complain about any aspect of the way you have been approached or treated during the study, the normal NHS complaints mechanisms are available to you.

Please visit www.nbt.nhs.uk/patients-carers/feedback for further information about how to make a complaint or contact the North Bristol NHS Trust Hospital Patient Advice and Liaison Service (PALS): Telephone 0117 414 4569. PALS can also provide confidential advice and support to patients, families and their carers.

Who should I contact if I have any questions? The study is being led by Dr Joanna Crofts at Southmead Hospital (North Bristol NHS Trust). If you have any questions about the study please contact Dr Joanna Crofts, Consultant Obstetrician, Southmead Hospital by contacting:



0117 4146764



TTT [@nbt.nhs.uk](mailto:TTT@nbt.nhs.uk)



Scanning this QR code will take you to the North Bristol NHS Trust
“Time-to-Transition Study” homepage.



**This leaflet has been developed in collaboration with the
Time-to-Transition Patient Partner Group**