# EDINBURGH PREGNANCY RESEARCH TEAM

## NEWSLETTER



EDINBURGH PREGNANCY RESEARCH TEAM

## Welcome...

... to the Summer Issue of the Edinburgh Pregnancy Research Team Newsletter



First things first.... do you like our new logo..?!

EPRT Edinburgh Pregnancy Research Team

We hope you enjoy our summer issue. See **page 4** for our latest trial - **ROTATE.** 

The Edinburgh Pregnancy Lesearch Team





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# **EPRT Update**

## The Edinburgh Pregnancy Research Team have had a busy few months!

#### 'Data Trusts: Lessons Learned and Future Directions' Symposium

On the 31st May EPRT Born in Scotland Data Trust attended the 'Data Trusts: Lessons Learned and Future Directions' Symposium which was a multi-disciplinary symposium bringing together academics. health researchers, information governance experts, policy makers, and fellow data intermediary pioneers, to share lessons learned from the Data Trust Initiative and consider future directions for trustworthy pilot projects. data governance.

### **Central Scotland Technical Conference**

Lothian

EPRT presented a poster for our Edinburgh Reproductive Tissue BioBank to the Central Scotland Technical Conference which was held in Glasgow on the 6th June.

### **Red 4 Research Day**

Red4Research Day is an annual event highlighting and celebrating research. Created by the NIHR (National Institute for Health and Care Research), this year it was held on Friday 16th June, with various activities happening throughout the week. EPRT joined other research teams based at RIE at a stall in the main RIE corridor. The lighthouse at Newhaven was even lit up red.

#### The Centre for Cardiovascular Science (CVS) Symposium

EPRT are part of the CVS within the University of Edinburgh. For this year's CVS Symposium, held on 15th June, we submitted a Born in Scotland and an Edinburgh Reproductive Tissue Biobank (ERTBB) poster. It was great to speak to our colleagues and the CVS Twitter feed used the hashtag #CVS2023 to live tweet about the event.





Research

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# **Coming Up!**

### for the Edinburgh Pregnancy Research Team

#### **METAFOR Trial**

EPRT will soon be recruiting for a new study, called METAFOR. Keep a look out for us opening this trial, which aims to find out if different formulations of metformin can provide the same benefits to mothers/gestational parents with less side effects for their baby. We plan to have more details in our next newsletter!

#### Lothian Health and Care Professions Research Conference

This conference, for healthcare professionals being held on 7th November, will be attended by the Edinburgh Pregnancy Research Team. We will present a *Born in Scotland* poster.



Born in Scotland Born in Scotland is hoping to open to recruitment in the Borders



#### Born in Scotland Data Trust

Born in Scotland Data Trust is planning some more focus groups. These focus groups will ask participants whether the Data Trust model may be better for governance of personal data such as that gathered from wearable technology (eg watches that record heart rate).





## Spotlight Study ROTATE Trial

ROTATE is a randomised controlled trial looking at manual versus instrumental rotation of the fetal head in malposition at birth.



## **ROTATE** Trial

Sometimes babies are not in the best position for a straightforward delivery at the time of birth and they need to be helped to rotate to fit through the birth canal. This can be done via a manual rotation (where the doctor uses their hands) or via an instrumental rotation (using an instrument such as forceps or a vacuum cup). There are pros and cons to each approach, and it is not clear which is the best to offer in terms of effectiveness and safety for mums and babies.

ROTATE is a randomised controlled trial looking at which of these methods is the safest and most effective at rotating a baby into optimal position for birth. This means that participants will be randomly allocated to either trying manual or instrumental rotation as the first approach to try and deliver the baby.





The trial is led by researchers from University College London, managed by the University of Birmingham Clinical Trials Unit and is currently recruiting at the Royal Infirmary of Edinburgh.

The goal is for a total sample of 5,200 women from approximately 40 sites.

To be eligible, potential participants must be fully dilated, need assistance with delivery and have a baby in a position that will require rotation to achieve delivery. Once consented, participants will be randomised to either manual or instrumental rotation at a 1:1 ratio, meaning that there is a 50% chance of being allocated to either arm.

The main aim of the study is to evaluate if manual rotation compared with instrumental

### **ROTATE Trial continued**

rotation reduces the risk of severe maternal perineal trauma, without substantially increasing the risk of caesarean section.

There are several secondary aims of the study including: evaluating successful vaginal birth with use of first method and evaluating other clinical differences between the two techniques including safety and experience of birth for both mother and baby.

We will be measuring outcomes using the following indicators:

 Primary: Third/fourth degree tear of maternal anal sphincter (superiority co-primary outcome).
Caesarean section (non-inferiority co-primary outcome).

· Secondary: Successful vaginal delivery with first instrument, neonatal morbidity, maternal childbirth experience, incontinence,

breastfeeding and post-traumatic stress disorder (PTSD) symptoms.

ROTATE is one of the newest studies to open in the RIE maternity department and so far we have had 3 recruits! We also recruited the 100th participant to the study and were rewarded with a lovely box of brownies from the trial team.





If you are a doctor or midwife working on labour ward and you would like to help telling patients about the trial and recruiting new participants, get in touch with the research team and we can get you set up!



### Stay tuned for updates as the trial progresses:

www.birmingham.ac.uk/research/bct

https://edin.ac/45DZZHN

researchmidwives @nhslothian.scot.nhs.uk

@RotateRct

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## Previous Research: C-STITCH

## Cerclage Suture Type for an Insufficient Cervix and its

### effect on Health

Comparing smooth and braided fibres for a stitch to keep the cervix closed

#### during early pregnancy

Every year, some women in the UK have complications where their cervix (the neck of the womb) becomes loose and opens during pregnancy. A stitch may be sewn into the cervix to try to keep it closed. This is called 'cervical suture' or 'cervical cerclage'. Without a stitch, the cervix can open too early, resulting in miscarriage or premature birth. Putting a stitch into the cervix does not guarantee to keep the cervix closed, but it can sometimes let the pregnancy continue for a few more weeks.

Prior to the C-STITCH trial, most UK consultants used braided threads simply because they have been used traditionally and are thought to be strong. But some surgeons were concerned that braided stitches might increase the risk of infection, which could spread upwards into the womb and cause serious complications during pregnancy for both the mother/gestational parent and the baby. The C-STICH study compared what happens in pregnancies when smooth or braided stitches are used.

C-STITCH was a multi-centre, randomised, controlled trial run by Birmingham Clinical Trials Unit, University of Birmingham across 75 sites. The trial was comparing monofilament to braided suture material used in cervical suturing. The primary outcome was whether braided suture material caused higher rates of infection which in turn led to pregnancy loss - miscarriage, stillbirth or neonatal death within a week of birth.



Reassuringly, there was no significant difference between pregnancy loss rates in either group; however monofilament sutures were associated with lower rates of maternal sepsis and chorioamnionitis. They were found to be more difficult to remove, with a higher chance of surgery under GA required for their removal.

For more information on C-STITCH see:

- www.birmingham.ac.uk/research/bctu/trials/womens/c-stich/index.aspx
- www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01808-6/fulltext
- https://edin.ac/3PpzsYX
- www.birmingham.ac.uk/news/2022/single-stranded-suture-threads-could-preventpregnancy-infection-complications-c-stich-trialfinds#:~:text=The%20C%2DSTICH%20trial%20results,infection%20developing%20durin g%20the%20pregn

## A quick update on

# Our Current Research Projects

**Born in Scotland in the 2020s** (BiS) is a cohort study in the pilot phase. It is currently recruiting in NHS Lothian, with plans to recruit participants from across Scotland. BiS is going very well and we now have over 570 participants. We are also working on the **Born in Scotland Data Trust** project - where we want to test how a new, different model for looking after data (called a data trust) could work in practice using BiS as a case study. More information is in our Born in Scotland Summer Newsletter - on our website or email the team for a copy!

Find out more: Born in Scotland - <u>https://edin.ac/4859Esz</u> Born in Scotland Data Trust - <u>https://edin.ac/3EsoSKm</u>

**STOPPIT-3** is a double-blind, randomised, placebo-controlled study which aims to resolve uncertainty about whether antenatal corticosteroids (ACS) reduces respiratory morbidity and NNU admission for twins. Women/people pregnant with twins having IOL or ELCS at 35+0-38+6 who meet the eligibility criteria can sign up, and those who have ELCS can also sign up to **STOPPIT-M**.

In **STOPPIT-M** we collect samples at the time of caesarean birth and want to find out why ACS work in some babies, but other babies still develop problems.

Find out more: https://edin.ac/3P7Vu0S

Edinburgh Reproductive Tissue Bio Bank (ERTBB) was set up to aid medical & scientific researchers working in the field of reproductive biology, with the long term goal of improving the health, diagnosis & treatment of women/gestational parents and their un-born infants.



medical data for researchers working on projects which have already obtained ethical approval from an appropriate ethics committee.

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Find out more: <u>https://edin.ac/45SLq2C</u>









### **Our Current Research Projects continued**

Our new **Small Baby Research Clinic** (set up following the success of our Metabolic Clinic and Preterm Birth Clinic) is going well. Those with a higher chance of having a small baby are referred. At birth, 8-10% babies are small. Most babies who measure small are growing normally (ie they are genetically small and their size is appropriate). However, we cannot always distinguish on ultrasound between a baby that is small but appropriately grown, and a baby

Small Baby Research Clinic

who has a small size due to their placenta not working as well. In this clinic we hope to improve on this, and those who attend can participate in research if they want to.

#### Find out more: <u>https://edin.ac/3Z4Db1i</u>



During pregnancy, the structure and function of the blood vessels throughout the body change. In pregnancy these changes may lead to complications, such as conditions like pre-eclampsia. The **I-Test** study is using Optical Coherence Tomography (OCT) which is a non-invasive scan of the back of the eye (retina). It is a simple and quick test that you may already have had during a trip to the opticians.

We have now demonstrated proof-of-principle (indicating that new retinal biomarkers may be able to be used for early detection of pregnancy

complications) and are about to scale up. These could then potentially be integrated into models that are predictive of the risk of stillbirth.

#### Find out more: <u>https://edin.ac/3P6brVr</u>

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The **ROTATE Trial** is a randomised controlled trial comparing manual rotation (where the doctor uses their hands) to instrumental rotation (using an instrument such as forceps or a vacuum cup) to see which of these methods is the safest and most effective at rotating a baby into optimal position for birth. Participants will be randomly allocated to either trying manual or instrumental rotation as the first approach to try and deliver the baby. There are several outcomes including perineal trauma and psychological wellbeing. **RIE recruited the 100th participant** (and received some delicious brownies to say thank you)!

Find out more: <u>https://www.birmingham.ac.uk/research/bctu/trials/womens/rotate/index.aspx</u> <u>https://edin.ac/45DZZHN</u>



#### VOL. 3



## Meet the Team

The Edinburgh Pregnancy Research Team (EPRT) encompasses a diverse group of academic researchers, medics, midwives and laboratory staff. We work together

within NHS Lothian and the University of Edinburgh to improve pregnancy outcomes and experiences through research. We also work collaboratively with many other academic and clinical teams and organisations, with the same shared interest in promoting research in pregnancy.



Professor Rebecca Reynolds Professor of Metabolic Medicine, University of Edinburgh; Honorary Consultant Physician, NHS Lothian



Dr Rosie Townsend Senior Research Fellow: Consultant Obstetrician, NHS Lothian



Jess Thompson **Research Midwife** 



Dr Marisa Magennis Research Coordinator; Project Manager



Em Thompson **Research Midwife** 

Sarah Donaldson

Research Midwife



**Professor Sarah Stock** 

Edinburgh

Personal Chair of Maternal and Fetal Health;

Fetal Medicine Subspecialist, Royal Infirmary

Consultant Obstetrician, NHS Lothian; Maternal and

Shona Low Senior Research Midwife



Anna Preston Research Midwife



Indira Kemp **Research Midwife** 



Wendy Mak **Research Practitioner** 



Dr Carlos Sánchez Soriano Research Fellow



**Dr Niamh McLellan Research Fellow** 



Irfa Rizwan PhD Student



**Dr Emily Frier** 

**Research Fellow** 

Jayne Brady

Technician





**Farah Francis** PhD Student



Jazz Kirkwood PhD Student



**Rosie Jenks Research Midwife** 



Dr Sarah Murray SCREDS Clinical Lecturer in Trainee in Maternal and Fetal



**Dr Fabienne Decrue** 







Senior BioBank

Obstetrics; Subspecialty Medicine, NHS Lothian



**Research Fellow** 



## Support Us



The Edinburgh Pregnancy Research Team is a group of health and science professionals, working across the University of Edinburgh and NHS. We are committed to promoting and supporting perinatal research in order to improve pregnancy outcomes and experiences for pregnant women and families.



You can help us by fundraising... while you shop!

The easiest way to do this is to go to our website: www.easyfundraising.org.uk/causes/eprt/



Easyfundraising partners with over 7,000 brands who will donate part of what you spend to a cause of your choice. It won't cost you any extra. The cost is covered by the brand.

Brands pay easyfundraising a commission because when you start your shop from the easyfundraising website or app, they can see we sent you to them. If you make a purchase, a commission is generated, and that gets turned into a donation for us - magic!

## **Keep in Touch!**

If you have any questions about our studies, would like further information or references for anything in this newsletter, please don't hesitate in contacting us. We would be delighted to hear from you!



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https://www.ed.ac.uk/edinburgh-pregnancy-research researchmidwives@nhslothian.scot.nhs.uk.

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