ISRCTN15732844 https://doi.org/10.1186/ISRCTN15732844

A clinical decision tool to improve pregnancy outcomes by improving risk assessment and maternity care

Submission date
03/06/2025

Recruitment status
Recruiting

Registration date
11/06/2025

Overall study status
Ongoing

Last Edited
11/06/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Every year in the UK, there are 25,000 pregnancies complicated by pre-eclampsia, 3000 stillbirths and 60,000 preterm births. Pre-eclampsia is a complication of pregnancy that can lead to serious long-term health problems for women and pregnant people and their children. Severe pre-eclampsia can be fatal to both mother and baby. Stillbirth is the death of a baby after 24 weeks gestation before or during birth. Preterm birth is when a baby is born before 37 weeks of pregnancy. The number of complications that occur varies from hospital to hospital, which may be due to differences in care provided for women and pregnant people.

We know that the families whose babies sadly die during pregnancy or birth carry that devastation forward for life. It can have an impact on the whole family, future choices and future pregnancies, relationships, and mental health. Stillbirth is not only a tragedy at the time, but a tragedy for a lifetime for families.

Preterm birth is responsible for the greatest number of deaths in children under the age of 5 years. We know that babies born premature may be vulnerable to problems. The earlier in the pregnancy a baby is born, the more vulnerable they are. It is possible for a baby to survive if born around 24 weeks of pregnancy onwards. Babies born this early need special care in a hospital with specialist facilities for premature babies, called a neonatal unit (NICU). The baby may have health and development problems because they have not fully developed in the womb. Some of these problems may be long-lasting and affect the child's quality of life. The impact of having a baby cared for in the NICU can be far-reaching. In the early days, the loss of the final trimester of pregnancy can result in feeding difficulties, anxiety of family disconnection, concerns about survival and long-term health outcomes, difficult decisions, feelings of hopelessness, financial pressures, and challenges learning to care for a tiny baby and becoming a parent in the NICU setting. The impact of preterm birth can last for years if there are long-term health issues. Mothers and birthing people of preterm infants have a higher chance of perinatal mental illness around the time of the birth.

There are three reasons why these pregnancy problems remain so common:

1. It is hard to identify which women are most likely to develop these complications, meaning that problems may develop unnoticed.
2. Risk assessment is often based on previous pregnancy outcomes, meaning that many parents

must experience complications before receiving specialist care.
3. NHS maternity staff struggle with lack of resources and it is hard for them to ensure they are using the latest national guidelines to provide the best care.
The Tommy's National Centre for Maternity Improvement has developed the Tommy's Pathway: a Clinical Decision Support Tool for use by women and pregnant people, midwives and doctors. The Clinical Decision Support Tool is provided as a web application which means it is accessed via an internet browser just like any other website, using either a desktop computer, laptop, smartphone or tablet (any device with access to the internet).
We aim to investigate whether the tool will reduce pre-eclampsia, stillbirth, and preterm birth by improving how we identify those at risk of these problems and then providing healthcare professionals with current national guidance on the best care to offer women and pregnant people.
This project includes a trial of The Tool, which is made up of a number of assessments which help to identify potential issues for women and pregnant people. These assessments have been demonstrated to be effective in other studies, but this trial will test the Tool as a whole package in a number of NHS hospitals across England. We will compare the number of women and pregnant people with pregnancy problems who have had care from hospitals using the Tool, with those not using the Tool. The results will help the NHS decide if the Tommy's Pathway: a Clinical Decision Support Tool reduces the number of pregnancy problems, and improves outcomes for mother and babies, and also if it saves the NHS money. If it does, its use will be recommended in all hospitals across the UK.
For health professionals to provide the best care for patients, randomised studies are needed to find out if treatments work. A randomised study involves assigning patients by chance to the treatment of interest, or to usual care, so that the effect of the treatment can be compared fairly. In this study, the whole hospital is randomised to deliver one intervention while another hospital will deliver standard care, to reduce the likelihood of patients being treated with a mixture of both interventions.
This study will aim to involve 62,400 NHS women and pregnant people in maternity units in England.
Half of the hospitals will use the Clinical Decision Support Tool to calculate the risk of pregnancy problems and provide associated care pathways, and half will carry on providing the care they offered before. All other aspects of care will be the same as the standard care provided by the hospital. Data will be collected on all women and pregnant people from the initial booking appointment until 28 days after the end of their pregnancy. Data will be collected from routinely collected hospital maternity records for both intervention and control units.
A specially gathered group of women, including those with lived experience of preterm birth, stillbirth and neonatal death and those without, have co-designed and developed the Tool from inception. To make sure the views of women are central to the way the study is done, PPI input involving women with lived experience and without will be sought through regular meetings during the set-up, delivery and dissemination of the results. Two patient representatives will sit on the Trial Steering Committee.
Our aim is to help make the UK the safest place in the world to give birth by improving women and pregnant people's access to best care and reducing the variations in care offered around the country.
If the Clinical Decision Support Tool is effective, it will be rolled out to other hospitals to reduce rates of pre-eclampsia, preterm birth and stillbirth across the UK. It will also be translated into non-English languages. We will make sure that the findings reach all the people who can benefit from them in a suitable format. This includes plain English summaries for the public and customised material for other people such as health professionals and NHS Trust managers. The Tommy's Centre for Maternity Improvement, with the support of the Royal Colleges, the Department of Health and Social Care and NHS England, will lead on developing plans for integrating the Clinical Decision Support Tool into all maternity care services.

Who can participate?
Anyone booking their pregnancy at a participating maternity unit

What does the study involve?
Each maternity unit will be assigned by chance to either the intervention or usual care. If the maternity unit is assigned to intervention, then everyone booking at the maternity unit will have the Clinical Decision Tool used to assess their risk of placental function and preterm birth. If the maternity unit is assigned to usual care they will continue with standard care pathways such as NICE.

What are the possible benefits and risks of participating?
In the maternity units using the intervention, the Clinical Decision Support Tool accurately calculates the woman's and pregnant person's risk of pregnancy problems at their first pregnancy visit with the aim of then providing "the right care at the right time, by the right healthcare professional". The Clinical Decision Tool could reduce pre-eclampsia, stillbirth, and preterm birth by improving how we identify those at risk of these problems and then providing healthcare professionals with current national guidance on the best care to offer women and pregnant people. This will mean that some women and pregnant people will avoid having unnecessary assessments and treatments, whilst others will be offered the additional monitoring and intervention they need.
All participating maternity units will contribute invaluable information as to how well the Tool works, how best to implement it and if it saves the NHS money to improve care for mothers and babies in the future.

Where is the study run from?
1. University of Bristol (UK)
2. Bristol Trials Centre - BTC (UK)

When is the study starting and how long is it expected to run for?
June 2023 to June 2026

Who is funding the study?
NIHR NHSX Artificial Intelligence Award (UK)

Who is the main contact?
1. Stefan Lewandowski
2. A/Professor Christy Burden
3. Professor Andrew Judge
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Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Christy Burden

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
327559

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 59197

Study information

Scientific Title
PregnAncy Risk assessmenT aNd dEcision suppoRt (PARTNER): a clinical decision support tool to reduce placental disorders and preterm birth in pregnancy

Acronym
PARTNER

Study objectives
Use of the Clinical Decision Tool will improve women and pregnant people’s access to best care and reduce the variations in care offered around the country.
If the Clinical Decision Support Tool is effective, it will be rolled out to other hospitals to reduce rates of pre-eclampsia, preterm birth and stillbirth across the UK.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/09/2024, HRA and Health and Care Research Wales (HCRW) (5 15 Castlebridge, 19 Cowbridge Road E, Cardiff, CF 11 9AB, United Kingdom; +44 (0)2920 230457; healthandcareresearch@wales.nhs.uk), ref: 24/EE/0042

Study design
Multi-centre randomized controlled cluster trial with embedded implementation and health economic analysis

Primary study design

Interventional

Study type(s)
Other, Efficacy

Health condition(s) or problem(s) studied
Hypertensive disorders in pregnancy

Interventions
Randomisation is performed by a member of the trial team via the 'Sealed Envelope' service. Sites are randomised 1:1 to either standard care or the Clinical Decision Support Tool. The randomisation is stratified by maternity unit size (either >4000 births or <4000) and blocked.

Maternity Trusts randomised to receive the Clinical Decision Support Tool will use the Tool to inform care pathway choices for women and pregnant people at those centres. The Clinical Decision Support Tool provides care pathway options based on best practice with evidence assimilated from all current national guidance available. It incorporates three algorithms for risk assessment and clinical decision support; one for placental disorders (preeclampsia, stillbirth) and two for the risk of preterm birth (one at the beginning of pregnancy and the other during pregnancy if women present with threatened preterm
labour), and two rule engines for change in fetal movements and timing of birth.

Maternity Trusts randomised to receive standard care will follow their usual care pathway protocols.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Clinical Decision Support Tool

Primary outcome(s)
Incidence of hypertensive disorders of pregnancy (pre-eclampsia or pregnancy-induced hypertension), measured at birth using:
1. The Clinical Decision Support Tool (intervention sites)
2. Extracts from local hospital systems (intervention and control sites)

Key secondary outcome(s))
Work Stream 1: the main trial
1. Stillbirth (fetal loss >24 weeks gestation)
2. Preterm birth (birth at <34 and <37 weeks of gestation)

Work Stream 2: implementation evaluation
1. Healthcare staff and women and pregnant people's experiences
2. Fidelity/reach/acceptability of the intervention

Work Stream 3: health economic evaluation
Health effects of the mother and child, together with health service costs accruing to both

Work Stream 1:
Fetal:
1. Birth weight and birth centile, birthweight >4000 g, LGA - birth centile >90th, and small for gestational age – SGA (birth centile <10th) measured at birth
2. Miscarriage (up to 23+6 weeks gestation) and stillbirth (death of baby after 24 weeks gestation before or during birth) measured at time of miscarriage or birth
3. Neonatal death (death ≤28 days of life) measured from birth to 28 days of life
4. Preterm birth (<34 and <37 weeks gestation of pregnancy) measured at birth
5. Gestational age (weeks) measured at birth
6. Neonatal complications: NICU admission; umbilical cord blood pH
7. Apgar score
8. Birth injury clavicle/humeral/skull fractures
9. Shoulder dystocia
10. Hypoglycaemia requiring NICU treatment
11. Respiratory distress
12. Fetal hyperbilirubinaemia measured at birth

Maternal:
1. Antepartum haemorrhage measured at booking until birth
2. Gestational diabetes mellitus measured at booking until birth
3. Mode of delivery (LSCS – emergency/elective/ID –forceps/ventouse/SVD) measured at birth
4. Obstetric anal sphincter injury (OASIS) measured at birth
5. Spontaneous labour/ Induction of labour (gestation in weeks and days and reason) measured at birth
6. Planned and Emergency Caesarean section, measured at birth
7. Eclampsia measured from the booking appointment until 28 days after birth
8. Stroke measured from booking appointment until 28 days after birth
9. Pulmonary Oedema measured from the booking appointment until 28 days after birth
10. Acute Kidney Injury measured from the booking appointment until 28 days after birth
11. Maternal Death measured from the booking appointment until 28 days after birth
12. Postpartum haemorrhage measured from the booking appointment until 28 days after birth
13. Admission to ITU, intubation and ventilation measured from the booking appointment until 28 days after birth
14. Antenatal maternal hospital stay (days)
15. Postnatal maternal hospital stay (days) measured from birth until 28 days post-birth

All outcome measures are collected from the maternity information system and/or the Clinical Decision Support Tool and are measured at birth unless otherwise specified

Completion date
01/06/2026

Eligibility

Key inclusion criteria
All women and pregnant people booked into participating NHS Trusts for maternity care:
1. NHS Trust with an active maternity unit
2. NHS Trust with >3000 births per year
3. IT system available for outcome data extraction
4. Internet access in clinical areas (including community settings)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Trust unwilling to participate
2. Trust using (or planning to use) the Fetal Medicine Foundation algorithm as part of their formalised standard care pathway

Date of first enrolment
01/07/2025

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal United Hospital Bath (maternity)
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
The Princess Alexandra Hospital
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR NHSX Artificial Intelligence Award

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes