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

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Last Edited 11/06/2025	<b>Condition category</b> Pregnancy and Childbirth	<ul><li>Individual participant data</li><li>[X] Record updated in last year</li></ul>

#### 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 preeclampsia 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 partner-trial@bristol.ac.uk

**Study website** https://partnertrial.blogs.bristol.ac.uk/

## **Contact information**

**Type(s)** Public, Scientific, Principal Investigator

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## Additional identifiers

**EudraCT/CTIS number** Nil known

**IRAS number** 327559

**ClinicalTrials.gov number** Nil known

**Secondary identifying numbers** 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

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#### 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

### Secondary study design

Cluster randomised trial

**Study setting(s)** Community, Hospital

**Study type(s)** Other, Efficacy

#### Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

#### 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

Pharmaceutical study type(s) Not Applicable

**Phase** Not Applicable

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

#### Primary outcome measure

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)

#### Secondary outcome measures

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

Overall study start date

01/06/2023

**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

**Age group** Adult

**Sex** Female

#### Target number of participants

A minimum of 13 maternity units in each group (31,200 women and pregnant people in the intervention group and 31,200 in the control group).

#### 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** England

United Kingdom

### 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

**Sponsor details** Beacon House Queens Road Bristol England United Kingdom BS8 1QU +44 (0)117 9289000 research-goverance@bristol.ac.uk

**Sponsor type** University/education

Website http://bristol.ac.uk/

ROR https://ror.org/0524sp257

## Funder(s)

**Funder type** Government

**Funder Name** NIHR NHSX Artificial Intelligence Award

### **Results and Publications**

Publication and dissemination plan

Intention to publish date 01/01/2027

### 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