

# The HEART-BEAT Clinic Study

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>05/02/2026   | <b>Recruitment status</b><br>Not yet recruiting       | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>10/03/2026 | <b>Overall study status</b><br>Ongoing                | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>24/02/2026       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The HEART-BEAT Clinic Study is focused on improving care and outcomes for pregnant women with heart conditions. Heart disease is a major cause of maternal death in the UK, and many of these deaths are thought to be preventable. For women with heart conditions, pregnancy can sometimes be a stressful experience with fragmented care pathways.

The primary goal of the HEART-BEAT Clinic Study is to explore the outcomes and experiences of women attending a specialist clinic that combines clinical care with research. With this information, we also hope to learn what kind of care best prevents poor pregnancy outcomes and use these findings to develop a better, patient-driven model of care for pregnant women with heart conditions that can be implemented around the UK and globally.

### Who can participate?

Women who are referred to our specialist Pregnancy Heart Clinic due to a heart condition or their risk of developing a heart condition.

### What does the study involve?

The study takes place primarily during regular clinic appointments, where participants will also complete up to two short questionnaires per visit. The study team will perform a heart rhythm check (ECG) and a heart ultrasound scan (echo) as per routine clinical care. Participants will also be asked for access to mother and baby health records to see patient health outcomes for up to 10 years after enrolment in the study, and the baby's health outcomes up to his/her first birthday.

Participants may be contacted about other add-on research studies that may involve additional interviews or health monitoring through devices like smart watches.

Patient involvement would end one year after delivery, and data linkage to routinely collected sources would continue for up to 10 years after delivery.

### What are the possible benefits and risks of participating?

This study will help us make new, improved recommendations for care pathways, ensuring that women with heart conditions remain safe and feel supported throughout their journey. The decision to join the HEART-BEAT study or any add-on studies will not impact clinical care, and there are minimal risks involved.

Where is the study run from?

The Rosie Hospital, the Cambridge University Hospitals NHS Foundation Trust, UK.

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

May 2026 to May 2046.

Who is funding the study?

1. Royal Papworth Hospital NHS Foundation Trust
2. NIHR Cambridge Biomedical Research Centre
3. The Harding Foundation

Who is the main contact?

Prof Catherine Aiken, cema2@cam.ac.uk

## Contact information

### Type(s)

Principal investigator, Scientific, Public

### Contact name

Prof Catherine Aiken

### ORCID ID

<https://orcid.org/0000-0002-6510-5626>

### Contact details

Department of Obstetrics and Gynaecology

Rosie Hospital

Robinson Way

Cambridge

United Kingdom

CB2 0SW

+44 01223333751

cema2@cam.ac.uk

## Additional identifiers

## Study information

### Scientific Title

The HEART-BEAT (Heart Evaluation and Assessment in Reproductive Transition – Biomarkers, Echocardiography, Adaptation, & Trajectories) Clinic Study

### Acronym

HEART-BEAT

### Study objectives

1. To explore the antenatal, labour, postnatal and neonatal experiences of women attending an integrated clinical-research pregnancy heart clinic
2. To explore the feasibility and acceptability of an integrated clinical-research pregnancy heart

clinic and explore patient views on the current provision of care and desired aspects of care

3. To explore the physiological changes of women attending an integrated clinical-research pregnancy heart clinic

4. To explore the antenatal, labour, postnatal and neonatal outcomes of women attending an integrated clinical-research pregnancy heart clinic

5. To understand how pregnancy care experiences and complications impact long term health outcomes of women attending an integrated clinical-research pregnancy heart clinic

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

notYetSubmitted

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study type(s)**

### **Health condition(s) or problem(s) studied**

Cardiac disease or cardiac risk factors in pregnancy

### **Interventions**

Participants will be asked for consent to extract data from their electronic health record for research purposes. This will include records from both the Pregnancy Heart Clinic and other services, including maternity services and neonatal services, that they access. Consent will cover data extraction from the electronic medical record of both mother and baby for up to 1 year after delivery.

Participants will be asked to complete validated questionnaires (e.g., Cambridge Worry Scale, Generalized Anxiety Disorder-7) at their Pregnancy Heart Clinic attendances. Participants will also be asked to complete bespoke questionnaires regarding their patient experience.

Participants will not be asked to complete more than two x 10 minute questionnaires per visit. Participants will also be asked for permission to link their study data (patient only) to routinely-collected data sources, including NHS (e.g. Hospital Episode Statistics, primary care data).

Participants will also be asked to consent to being contacted about other ethically approved studies either (i) during their pregnancy or (ii) after pregnancy. These may involve participating in qualitative interviews or completing additional questionnaires. During pregnancy, add-on studies may involve additional testing arranged during clinic visits, for example, 6-minute walk tests or data collection from wearable heart monitors ('smart watches'), which are for research purposes and will not be used to inform clinical care. Specific ethical approval and consent will be obtained for each 'add-on' study either during or after pregnancy.

### **Intervention Type**

Other

### **Primary outcome(s)**

1. Maternal experience following attendance at the HEART-BEAT Clinic measured using standardised patient experience tools and standardised assessment tools of maternal anxiety

and psychological symptoms at initial visit, pre-delivery, 6-8 weeks postpartum, 1 year postpartum

### **Key secondary outcome(s)**

1. Maternal outcomes during and after pregnancy measured using clinical diagnoses, heart structure and function (echocardiogram, electrocardiogram) at initial visit, pre-delivery, 6-8 weeks postpartum, 1 year postpartum

2. Neonatal outcomes measured using gestation and mode of birth, the birthweight and admission to neonatal intensive care unit at 6-8 weeks postpartum, 1 year postpartum

### **Completion date**

01/05/2046

## **Eligibility**

### **Key inclusion criteria**

1. Women referred to a regional cardiac service because they have cardiac disease or cardiac risk factors
2. Women who are currently pregnant, have been pregnant within the past year, or are intending to become pregnant

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

16 years

### **Upper age limit**

100 years

### **Sex**

Female

### **Total final enrolment**

0

### **Key exclusion criteria**

1. Less than 16 years of age
2. Anyone who lacks the capacity to consent

### **Date of first enrolment**

01/05/2026

### **Date of final enrolment**

30/04/2036

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

### Rosie Hospital

Robinson Way

Cambridge

England

CB2 0QQ

# Sponsor information

## Organisation

Cambridge University Hospitals NHS Foundation Trust

## ROR

<https://ror.org/04v54gj93>

## Organisation

University of Cambridge

## ROR

<https://ror.org/013meh722>

# Funder(s)

## Funder type

## Funder Name

Royal Papworth Hospital NHS Foundation Trust

## Alternative Name(s)

Royal Papworth Hospital NHS FT, Royal Papworth Hospital, RoyalPapworth, Royal Papworth Hospital | East of England, PAPWORTH HOSPITAL NHS FOUNDATION TRUST CHARITY, royal papworth hospital charity, Royal Papworth Hospital Nhs Foundation Trust

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

**Funder Name**

NIHR Cambridge Biomedical Research Centre

**Alternative Name(s)**

Cambridge Biomedical Research Centre, NIHR Cambridge BRC, National Institute for Health Research Cambridge Biomedical Research Centre

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

United Kingdom

**Funder Name**

Harding Foundation

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available