

# Children of the UK Pregnancies Better Eating and Activity Trial

<b>Submission date</b> 09/02/2023	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/04/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Population studies and animal models suggest that maternal obesity is associated with early evidence of cardiovascular problems in children. Observations of a higher heart rate and early signs of heart complications (by MRI) in newborns of women with obesity compared to those of normal-weight women support these findings. A few years ago a study (UPBEAT) in over 1500 obese pregnant women showed that an intervention which improved diet and physical activity reduced their weight gain and fat mass. Most recently, a study of their 3-year-old children found, using heart ultrasound scans, evidence of abnormal structure and function, which was prevented by the improved maternal diet and physical activity. Therefore, the Children of UPBEAT study is aiming to once more recruit UPBEAT mothers and their children to better understand the relationship between maternal obesity and offspring cardiovascular health.

### Who can participate?

Women who took part in the UPBEAT study during their pregnancy and their 9-11-year-old children

### What does the study involve?

The study involves participants completing some online questionnaires before visiting the study team at their local hospital for a short visit. At the hospital, children and their mothers will have their height, weight, and other basic body measurements taken. Both children and their mothers will also have a small amount of blood taken and have their blood pressures assessed to get a better picture of their metabolic health status. Children will also have a scan to measure their body composition (muscle and fat), an ultrasound scan of their heart and blood vessels, have their heart rate measured by electrocardiography (ECG), and perform an easy fitness test. After the visit, children will wear a wrist-worn heart rate monitor and small blood pressure monitor for 24 hours to understand how their heart functions during normal, daily life.

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

The tests will provide a detailed view of the participants' hearts and blood vessels. While the information gathered is for research, it may be possible that additional information is gained which may be helpful in guiding children's future health, although it is expected that there would only be rare occasions when this was the case. The study will help us better understand

the benefits for children of a healthy and active lifestyle when mothers are pregnant. However, as the structure and function of the heart can change over time, a normal result from these scans cannot completely rule out heart problems in the future. There are no known risks from any of the tests performed as part of this study. However, participants may experience some minor discomfort/bruising due to blood sampling.

Where is the study run from?  
King's College London (UK)

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

Who is running the study?  
British Heart Foundation (UK)

Who is the main contact?  
Prof. Paul Taylor, [childrenofupbeat@kcl.ac.uk](mailto:childrenofupbeat@kcl.ac.uk)

## Contact information

**Type(s)**  
Principal investigator

**Contact name**  
Prof Paul Taylor

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
308663

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

SP/F/21/150013, CPMS 56123

## Study information

### Scientific Title

A study of cardiovascular function in 10-year-old children of obese women who participated in an antenatal lifestyle intervention

### Acronym

Children of UPBEAT

### Study objectives

The UPBEAT randomized control trial (RCT) was a study of 1555 obese pregnant women who were randomized in early pregnancy to a behavioural intervention (diet and physical activity) or to standard antenatal care across multiple UK centres. Children born to obese mothers are known to have adverse cardiovascular outcomes in adulthood. A small sub-study has previously shown that the UPBEAT RCT may confer protection against early adverse cardiovascular remodelling. The hypothesis is that a lifestyle intervention in women with obesity will improve cardiovascular outcomes in their 9-11-year-old children.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 02/06/2023, London - Brighton & Sussex REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8140; brightonandsussex.rec@hra.nhs.uk), ref: 23/LO/0410

### Study design

Observational multicentre longitudinal 10-year follow-up of a randomized controlled trial

### Primary study design

Observational

### Study type(s)

Prevention

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

Prevention of early adverse cardiovascular remodelling in children born to obese mothers

### Interventions

The original UPBEAT RCT involved obese pregnant women who were randomized in early pregnancy to a behavioural intervention (diet and physical activity) or to standard antenatal care.

The Children of UPBEAT study will include a comprehensive cardiovascular assessment (transthoracic echocardiogram [cardiovascular structure and function], vascular ultrasound [carotid intima-media thickness], pulse-wave velocity [arterial stiffness], clinic and ambulatory

blood pressure, and clinic and ambulatory heart rate variability [autonomic function]). Cardiometabolic profiling will be done by blood sampling. Body composition will be assessed by dual-energy X-ray absorptiometry (DEXA) and anthropometrics. A sub-maximal cardiorespiratory fitness test will be done. Questionnaires will be used to assess diet, physical activity, and education attainment.

Mothers will complete anthropometry, blood sampling, and questionnaires.

### **Intervention Type**

Other

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

Current primary outcome measure as of 09/04/2025:

Interventricular septal wall thickness using transthoracic echocardiography at a single timepoint

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Previous primary outcome measure:

Left ventricular mass measured using transthoracic echocardiography at a single timepoint

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

Measured at a single timepoint:

1. Blood pressure and heart rate variability measured during clinical visits and by ambulatory monitors over 24 hours
2. Cardiac structure and function measured using transthoracic echocardiography
3. Arterial stiffness measured using pulse-wave velocity
4. Carotid intima-media thickness measured using vascular ultrasound
5. Body composition analysis measured using dual-energy X-ray absorptiometry (DEXA) and anthropometry
6. Cardiorespiratory fitness estimated using a sub-maximal fitness test

### **Completion date**

30/01/2026

## **Eligibility**

### **Key inclusion criteria**

Women who took part in UPBEAT during their pregnancy and their 9-11-year-old children

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Sex**

All

**Key exclusion criteria**

1. Inability and unwillingness to provide informed consent
2. Any major health problems which may impact the development of the cardiovascular system or body composition
3. Women and their children who did not take part in the previous UPBEAT study

**Date of first enrolment**

01/03/2023

**Date of final enrolment**

31/03/2026

**Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**

**St Thomas' Hospital**

Westminster Bridge Road

London

United Kingdom

SE1 7EH

**Study participating centre**

**Glasgow Royal Infirmary**

Wolfson Medical School Building

University Avenue

Glasgow

United Kingdom

G12 8QQ

**Study participating centre**

**Newcastle Royal Infirmary**

Institute of Cellular Medicine

3rd Floor, William Leech Building

The Medical School

Newcastle University

Newcastle

United Kingdom  
NE2 4HH

**Study participating centre**  
**St Mary's Hospital**  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

## Sponsor information

**Organisation**  
King's College London

**ROR**  
<https://ror.org/0220mzb33>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
British Heart Foundation

**Alternative Name(s)**  
the\_bhf, The British Heart Foundation, BHF

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United Kingdom

## Results and Publications

## Individual participant data (IPD) sharing plan

Data collected for this study, including individual participant data and a data dictionary defining each field in the set, will be made available to others, upon request following publication. Proposals to use data from the UPBEAT RCT are considered by the UPBEAT Scientific Committee. In the first instance, scientists interested in using these data should contact the Children of UPBEAT principal investigator Prof Paul Taylor at paul.taylor@kcl.ac.uk

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes