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Children of the UK Pregnancies Better Eating and Activity Trial

Submission date
09/02/2023

Recruitment status
Recruiting

Registration date
03/04/2023

Overall study status
Ongoing

Last Edited
09/04/2025

Condition category
Circulatory System

[ ] 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
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

Study website
https://www.medscinet.net/upbeat/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Paul Taylor

ORCID ID
http://orcid.org/0000-0002-4740-4307

Contact details
Department of Women and Children’s Health
School of Life Course and Population Sciences
Faculty of Life Sciences & Medicine, King’s College London &
Women’s Health Academic Centre
King’s Health Partners
10th Floor, North Wing, St Thomas' Hospital
1 Westminster Bridge
London
United Kingdom
SE1 7EH
+44 (0)20 7188 3630
paul.taylor@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
308663

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2023

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

Age group
Child

Sex
Both

Target number of participants
300

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
England

Scotland

United Kingdom

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

Sponsor details
Research Governance Office
Research Management and Innovation Directorate (RMID)
King's College London, Waterloo Campus
3rd Floor
5-11 Lavington Street
London
England
United Kingdom
SE1 0NZ
-
rgo@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

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

Publication and dissemination plan
The research results will be published in high-impact peer-reviewed journals and will be presented at national and international conferences.

More details can be found at https://medscinet.net/upbeat/

Participants will receive newsletters highlighting the latest updates and results of the study.

Intention to publish date
31/01/2027

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