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UK Pregnancies Better Eating and Activity Trial

Submission date
23/07/2008

Recruitment status
No longer recruiting

Registration date
28/11/2008

Overall study status
Completed

Last Edited
29/07/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

You can't open a paper or watch TV today without hearing that people are heavier than previous generations, and that this increase in weight leads to health problems. Many women who are heavy when they become pregnant have no problems in pregnancy and deliver a healthy baby. At the moment no one can predict those women at greatest risk. But we do know that heavier women are more at risk of pregnancy complications than women who are thinner. These complications include miscarriage, gestational diabetes and high blood pressure in pregnancy for the mother. At the same time the baby can grow excessively and be larger than expected, sometimes the baby can grow more slowly and therefore be smaller than expected, and both can cause problems during delivery for the mother and the baby. We also know that being born too large or too small can have health consequences that last well into childhood and beyond. We want to see if we can develop an antenatal programme that improves the outcomes for women and their babies. This will need to include advice about what you eat and the physical activities you feel able to do, and enjoy, in pregnancy. The dietary advice will be about food we believe will be better for you to eat rather than a 'diet' in the usual meaning, as weight loss in pregnancy has not been linked to better outcomes. The exercise advice will be tailored to your fitness level. There are many experts involved in this project, including nutritionists, psychologists, activity experts, service evaluators, midwives and health trainers. In order to work out what works best, in terms of what pregnant women should eat and how much and what type of activity works for them, we have talked to women but now need to ask a group of women to try this out for us. This will involve talking to the study midwife or health trainer every week, and putting the dietary and activity advice we think will work into practice. We want to know if our ideas work for real women with busy lives. You will be asked how following the plan fits in with your life, so we will therefore be very interested in how it works for you. You will therefore be asked to complete questionnaires about this. Once we have worked out what works best for women and could become part of routine antenatal care we will test this in a large clinical trial. What we want you to think about is whether you would be prepared to help us in this first testing of the advice.

Who can participate?

You have been asked to take part because you are pregnant and had a body mass index (BMI) of 30 or more when you first saw your midwife or doctor.

What does the study involve?
You will be seen by a research midwife who will answer any questions you may have. Once you have agreed to take part you will be asked to sign a consent form and be given a copy of this to keep. The midwife will ask you about your past medical and obstetric history. You will also be asked about your current eating and physical activity. You will be asked to wear a monitor that measures your activity for 7 days. This will be repeated on two more occasions during your pregnancy. You will be asked to take part in the study and will be asked what you think about it. The midwife will also take a blood sample from you when you first take part, at 28 weeks (6 months) and again at around 34 weeks (about 6 weeks before your baby is due). You will also have a glucose tolerance test at 28 weeks. This is often done on pregnant women to see how their bodies are handling the blood sugar levels. When you return the monitor, about a week after the first appointment, you will be put into one of two groups. Group 1 will have routine antenatal care and see the midwife two more times, and group 2 will see a health trainer and meet other women in the study weekly for 8 weeks. At these sessions advice and information about healthy lifestyle choices will be discussed. At all of these appointments information will be collected about what you are eating and the activities you are doing. You may be asked to wear a monitor for some of the time to measure your activity level. All of this will be in addition to your normal antenatal care, although wherever possible we will arrange visits to suit you, and they may take place in the hospital, at your GP surgery, in another venue close to your home or may even be in your home. We would also like to speak to your partner and take a blood sample from him, although you can still take part even if he does not want to. When you have had your baby we would like to record details about your pregnancy and delivery, including measurements from your baby and a blood sample from the umbilical cord, or the baby's saliva sample. We will also ask you if you agree to your baby having a special scan to help us work out how new babies store their body fat. This scan is called a PeaPod. We would also like to see you and your baby when he/she is 6 months old. At this appointment we will measure and weigh your baby and ask about feeding since birth. At this time we would also like to weigh and measure you and ask you questions about food and activity.

What are the possible benefits and risks of participating?
You may not benefit personally from taking part, but your participation may help with the planning of an effective antenatal programme that improves the outcome of pregnancy for many women in the future, and influence the health of their children for the whole of their life. The main side-effect is that we will need your time. We will want to stay in touch with you throughout your pregnancy and we appreciate how busy pregnant women are.

Where is the study run from?
St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2008 to March 2017

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Improving pregnancy outcome in obese women; a multicentre randomised controlled trial

Acronym
UPBEAT

Study objectives
Current study hypothesis as of 06/06/2012:
This study hypothesises that a complex intervention focussing on dietary glycemic load and physical activity delivered over a period of 8 weeks during pregnancy in obese women will lead to a reduction in Gestational Diabetes Mellitus, (GDM) and a lower incidence of macrosomia.

Previous study hypothesis:
This study will aim to develop a complex intervention that will lead to the improvement of pregnancy outcome in obese pregnant women. Through individualised dietary and physical activity regimes we aim to improve maternal glucose sensitivity in obese pregnant women and thereby reduce the incidence of maternal, foetal and neonatal complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Westminster, 03/02/2009, ref: 09/HO802/5

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity during pregnancy

Interventions
Current interventions as of 0/06/2012:
The intervention is delivered by a health trainer in weekly sessions between 20 and 28 weeks' gestation and focusses on changing the diet (lowering the glycemic load, free sugars and saturated fat intake) with advice on increasing mild to moderate physical activity. Each session comprises a targetted dietary and physical activity change with individualised SMART goals.

Women in the control arm will receive standard antenatal care. All women have an OGTT at 28 weeks.

Previous interventions:
The intervention consists of an individualised activity and diet plan. Women will be recruited between 10 - 16 weeks gestation and the interventions will continue until delivery. Therefore maximum duration for any one woman would be 32 weeks (allowing for her to deliver at 2 weeks post-estimated date of delivery).

Women in the control arm will have blood taken at recruitment and again in late pregnancy. Other than this they will receive usual pregnancy care and advice in accordance with local and national antenatal care guidelines.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure(s):
1. Maternal: GDM by HAPO criteria.
2. Infant: macrosomia (>90th customised birthweight centile).

Previous primary outcome measure(s):
Improved maternal glucose sensitivity, assessed at recruitment (10 - 16 weeks), and again in the third trimester (32 - 36 weeks).

Key secondary outcome(s)
Current secondary outcome measure(s):
1. Maternal: complications in pregnancy (inc GDM, pre-eclampsia, depression, quality of life),

physical activity, diet, gestational weight gain, maternal body composition (skin folds), mode of delivery, hospital admissions. Health economic assessment.
2. Infant: adverse outcomes, neonatal unit admissions, SGA, LGA, body composition (skin folds).
3. At 6 months post partum: maternal and child diet and physical activity. Maternal general health (inc depression, quality of life). Maternal and child body composition. Childhood modifiers /modulators of obesity.
4. 3 years: To be confirmed; measures of maternal and child body composition, diet, physical activity. Childhood mental health, cardiovascular function.

Previous secondary outcome measure(s):
Reduction in foetal, maternal and pregnancy complications, assessed at recruitment (10 - 16 weeks), and again in the third trimester (32 - 36 weeks).

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent
2. Pregnant women with booking body mass index (BMI) greater than or equal to 30 kg/m^2
3. Singleton pregnancy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
1158

Key exclusion criteria
Current exclusion criteria as of 06/06/2012:
1. Unwilling or unable to give informed consent
2. Pregnant women with booking BMI less than 30 kg/m^2
3. Multiple pregnancy
4. Pre-existing diabetes mellitus
5. Pre-existing hypertension requiring treatment, pre-existing thyroid and renal disease, current psychosis, sickle cell disease, thalassemia, coeliac disease

Previous exclusion criteria:
1. Unwilling or unable to give informed consent
2. Pregnant women with booking BMI less than 30 kg/m^2

3. Multiple pregnancy
4. Pre-existing diabetes mellitus

Date of first enrolment
01/11/2009

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Guy's and St. Thomas' Charity

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Seventh Framework Programme

Alternative Name(s)
Seventh framework programme of the European Community for research and technological development and demonstration activities (2007-2013), FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/07/2013		Yes	No
Results article	pilot study results	01/02/2014		Yes	No
Results article		01/08/2014		Yes	No
Results article		01/10/2015		Yes	No
Results article		29/11/2016		Yes	No
Results article		01/01/2018		Yes	No
Results article		21/01/2019		Yes	No
Results article	maternal altered lipid metabolism and associations with offspring adiposity	31/03/2022	01/04/2022	Yes	No
Results article		12/10/2022	13/10/2022	Yes	No
Results article	Secondary analysis of clinical history and clinical /anthropometric measures	30/12/2022	03/01/2023	Yes	No
Results article	subgroup assessment	23/03/2023	24/03/2023	Yes	No
Protocol article		18/02/2014		Yes	No
Other publications	Secondary analysis	24/07/2024	29/07/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes