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Pregnancy, Exercise And nutrition Research study with app support

Submission date
11/12/2012

Recruitment status
No longer recruiting

Registration date
21/01/2013

Overall study status
Completed

Last Edited
13/05/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Overweight, body mass index (BMI) ≥ 24.9 kg/m2 and obesity (BMI ≥ 30 kg/m2) carry a huge health burden both on the individual and on society. About 5 out of 10 women of reproductive age are either overweight or obese and this increases the risk of adverse pregnancy and fetal outcomes. For the mother, there is a higher incidence of pre- eclampsia, gestational diabetes and operative intervention at the time of delivery such as caesarean section and instrumental delivery. Problems that can arise in the baby include macrosomia [newborn with an excessive birth weight (baby > 4kg at birth)], shoulder dystocia [occurs when the baby's head has been born but one of the shoulders becomes stuck behind the mother's pelvic bone], birth injury and admission to the special care baby unit. These adverse outcomes correlate with increasing BMI, increasing gestational weight gain, higher maternal blood glucose levels and gestational diabetes. This study will examine the effect of a "healthy lifestyle package with app support" compared with routine pregnancy care on pregnancy outcomes. The "healthy lifestyle package with app support" includes a combination of a healthy diet, an exercise intervention with a smart phone application as an information and motivational source for overweight and obese women in pregnancy. The primary aim is to assess the impact of the "healthy lifestyle package with app support" on development of gestational diabetes when compared to routine antenatal care.

Who can participate?
Women with singleton pregnancies between 10-15 weeks gestation between the ages of 18-45 with a smartphone, and a BMI of greater than 25 kg/m2

What does the study involve?
Women will be randomly assigned into two groups: an intervention group and a control group. Women in the intervention group will have standard antenatal care but will receive a particular healthy lifestyle package with app support. This package includes a combination of a healthy diet, an exercise intervention with a smart phone application as an information and motivational source for overweight and obese women in pregnancy. The control group will receive a 'regular lifestyle package', which will consist of standard antenatal care and general advice on weight gain according to BMI.

What are the possible benefits and risks of participating?
The benefits for participating are numerous. These include lower glucose levels and less gestational weight gain. The study aims to motivate and change behaviors in order to lead a healthier lifestyle, which will reduce the risk of obstetric and fetal complications as mentioned above and improve long-term health. There will also be an additional scan of the baby to assess growth at 34 weeks. Studies have shown that there are absolutely no risks to the mother or her baby from taking part in a healthy diet and sensible exercise plan during pregnancy.

Where is the study run from?
The study will run from the National Maternity Hospital (Ireland)

When is the study starting and how long is it expected to run for?
The trial is starting in January 2013 and is expected to run for 2 years.

Who is funding the study?
National Maternity Hospital medical fund (Ireland)

Who is the main contact?
Prof. Fionnuala McAuliffe PI
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Pregnancy, Exercise And nutrition Research study with app support: A randomized controlled trial

Acronym

PEARs

Study objectives
The introduction of a 'healthy lifestyle package with app support for overweight and obese women in pregnancy could reduce the incidence of gestational diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Maternity Hospital, Holles St, Dublin 2, 15/10/2012

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pregnancy/overweight/obesity/gestational diabetes

Interventions
1. Recruitment according to above criteria
2. Written and informed consent
3. Randomization will occur into the intervention and control groups.

The intervention group will receive a "Healthy lifestyle package" which consists of targeted advice on a low GI eucaloric diet, individualized exercise goals and a specially designed smartphone application containing daily information about nutrition, and exercise delivered in a motivational way.

The control group will receive usual care or "regular lifestyle group".

At randomization:
1. Maternal anthropometry
2. 3-day food diary, International Physical Activity Questionnaire (IPAQ) and stages of change questionnaire
3. Fasting glucose
4. Intervention group- individual and group education sessions on the healthy lifestyle package as outlined above
5. Control group will receive routine antenatal care which does not include specific nutritional advice nor specific advice on gestational weight gain 24 weeks
6. Research team to be in contact with the intervention group every 2 weeks to support adherence to exercise goals and low GI diet.

28 weeks:
1. Maternal weight recorded
2. Glucose Tolerance Test (GTT)

3. IPAQ, stages of change questionnaire
4. 3 day food diary

34 weeks:
1. Maternal weight recorded
2. Ultrasound for fetal growth
3. 3 day food diary, compliance questionnaire, IPAQ, stages of change questionnaire

Delivery:
1. Cord bloods for glucose
2. Birthweight, Ponderal Index (PI)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
incidence of gestational diabetes according to the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) criteria at 29 weeks

Key secondary outcome(s))
1. Gestational weight gain
2. Maternal Glycemic Index (GI) value
3. Maternal activity levels in the 3rd trimester

Completion date
30/08/2016

Eligibility

Key inclusion criteria
1. Singleton pregnancies with a live fetus
2. Smartphone
3. Women between the ages of 18 and 45 at 10-15 weeks gestation with an early pregnancy body mass index (BMI) ≥ 25 kg/m2
4. Women with adequate understanding of the English language and an understanding of the study to enable them to give informed consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
Female

Key exclusion criteria
1. Multiple Pregnancy
2. Women < 18 or >45 years of age
3. Those with pre gestational diabetes or early onset gestational diabetes mellitus or past history of gestational diabetes
4. Fetal anomaly
5. Previous stillbirth/perinatal death
6. Those whose English is inadequate or those who are unable to understand the study adequately to participate
7. Those with a medical disorder requiring medication

Date of first enrolment
01/03/2013

Date of final enrolment
30/01/2016

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Dublin
Ireland
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Sponsor information

Organisation
National Maternity Hospital (Ireland)

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Maternity Hospital (Ireland) - Medical Fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2018		Yes	No
Results article	secondary analysis results	12/05/2021	13/05/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes