ISRCTN31045925 https://doi.org/10.1186/ISRCTN31045925

The HEALTHY study: Healthy Eating, Exercise And Lifestyle Trial for pregnant women for the control of fasting blood glucose

Submission date
19/09/2013

Recruitment status
No longer recruiting

Registration date
31/10/2013

Overall study status
Completed

Last Edited
11/10/2017

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
Gestational Diabetes Mellitus (GDM) is diabetes that is diagnosed during pregnancy, and affects 3-6% of women who deliver a baby in Ireland. GDM has a serious impact on the woman and her baby. She is more likely to require induction of labour or a caesarean section, and the diagnosis has a 7-fold increase in the risk of developing type 2 diabetes mellitus. Potential complications for the baby include stillbirth, malformations at birth, excessive accumulation of fat, low blood sugar after birth and an increased risk of childhood obesity. GDM is now diagnosed more often in Ireland because of stricter guidelines and prompt screening, which is based on risk factors. The mother may get GDM due to family history, previously delivering a large baby, and maternal obesity. Arguably, obesity is the most important risk factor because it is common and potentially modifiable. About one in six women booking for antenatal care in Ireland today is obese which places them at high risk of GDM. The aim of this study is to find out whether a programme of intensive, supervised exercise classes, providing information on diet and lifestyle, starting early in the second trimester, will improve an obese womans fasting glucose levels at 24-28 weeks of pregnancy.

Who can participate?
Overweight women attending the hospital for their first visit between 10 and 17 weeks of pregnancy

What does the study involve?
Participants will be randomly allocated to one of two groups: intervention or non-intervention. The intervention group will be asked to attend three exercise classes per week, and will continue receiving standard antenatal care. The non-intervention group will continue their pregnancy receiving standard antenatal care alone. Assessments of the pregnant woman and her baby (measurements of weight and body composition, blood tests, and lifestyle and quality of life questionnaires) will be performed at 24-28 weeks and 35-38 weeks of pregnancy, and at 6 weeks after childbirth.

What are the possible benefits and risks of participating?
Exercise in pregnancy has been shown to be safe. Participants are coached during classes on how intensely, how often, and what exercise they should be doing. Benefits to exercising during pregnancy are both physical and psychological.

Where is the study run from?
Coombe Women and Infants University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start towards the end of 2013. Participants will be enrolled in the study from 10-17 weeks of pregnancy to 6 weeks after giving birth; however, the study will extend beyond this as we intend to follow the participants and their infants health over a longer period.

Who is funding the study?
The Coombe Women and Infants University Hospital (CWIUH) (Ireland) and University College Dublin (UCD) (Ireland)

Who is the main contact?
Prof. Michael J Turner
michael.turner@ucd.ie

Contact information

Type(s)
Scientific

Contact name
Prof Michael J Turner

Contact details
UCD Centre for Human Reproduction
Coombe Women and Infants University Hospital
Cork Street
Dublin
Ireland
Dublin 8

Additional identifiers

EudraCT/CTIS number
2013-004066-33

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
26-2011

Study information

Scientific Title
HEALTHY: a single-blinded, randomised, controlled trial for pregnant women with a BMI >29.9kg /m2; healthy eating, exercise and lifestyle intervention and standard antenatal care versus standard antenatal care alone for the control of fasting blood glucose

Acronym
HEALTHY

Study objectives
Current hypothesis as of 16/09/2014:
It is hypothesised that in pregnant women with a BMI >29.9 kg/m2, an intervention, commencing early in the second trimester, of healthy eating, exercise and lifestyle change, through regular group exercise classes and standard antenatal care, will result in a 24-28-week mean fasting glucose level that is 0.4 mmol per litre lower than that of the group receiving standard antenatal care alone.

Previous hypothesis:
It is hypothesised that in pregnant women with a BMI >29.9 kg/m2, an intervention, commencing early in the second trimester, of healthy eating, exercise and lifestyle change, through regular group exercise classes and standard antenatal care, will result in a 28-week mean fasting glucose level that is 0.4 mmol per litre lower than that of the group receiving standard antenatal care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coombe Women and Infants University Hospital Research Ethics Approval, October 2012, ref: 26-2011

Study design
Single-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Gestational diabetes, obesity in pregnancy

Interventions
Current interventions as of 16/09/2014:
Once women are included in the study, they will be randomised into one of two groups: exercise intervention or non-intervention (standard antenatal care).

The exercise intervention will be an established group exercise programme taught by principal investigator and research fellow Dr Niamh Daly who is a certified trainer, and a trainee Obstetrician and Gynaecologist on the Specialist Training Scheme.

The class will be a training programme package of exercise: aerobic and resistance training in addition to promotion of healthy lifestyle choices, such as smoking cessation, minimising alcohol intake and abstaining from processed 'junk' foods.

The exercise programme promotes healthier patterns of eating and living but does not emphasise limiting energy intake. The advice is repeated, re-enforced and positive, in the form of promotion of healthy fresh foods (high-quality protein [fresh meat/poultry/eggs/fish], low-glycaemic index, fresh fruit and vegetables and nuts, choosing low-fat over full-fat products, smoking cessation, minimising alcohol intake), with recipe, website, literature and other resource suggestions usually as part of a group discussion towards the last 5 minutes of each hour-long class.

Standard antenatal care
Standard antenatal care for obese pregnant women is usually combined antenatal care between hospital and GP. With a BMI >29.9 kg/m2, they are ineligible for midwifery-led care. Visits are alternated until late pregnancy when all pregnancy visits are with an obstetrician in the hospital. As part of routine antenatal care, fasting bloods and Oral Glucose Tolerance Tests (OGTTs) are taken at 24-28 weeks to screen for gestational diabetes mellitus.

Fasting bloods will also be performed in all participants at 10-17 weeks gestation, 24-28 weeks gestation, 35-38 weeks gestation and 6-8 weeks postpartum to observe patterns and differences within and between the two groups.

A sample size of 24 per arm is required to have at least 80% power to detect a clinically meaningful difference of 0.4 mmol/L with a level of significance of 0.05.

Previous interventions:
Once women are included in the study, they will be randomised into one of two groups: Exercise intervention or non-intervention (standard antenatal care).

The exercise intervention will be an established group exercise programme taught by principal investigator and research fellow Dr Niamh Daly who is a certified trainer, and a trainee Obstetrician and Gynaecologist on the Specialist Training Scheme.

The class will be a training programme package of exercise: aerobic and resistance training consisting of constantly varied, modified-intensity, functional movements; in addition to promotion of healthy lifestyle choices, such as smoking cessation, minimising alcohol intake and abstaining from processed 'junk' foods.

The exercise programme promotes healthier patterns of eating and living but does not emphasise limiting energy intake. The advice is repeated, re-enforced and positive, in the form of promotion of healthy fresh foods (high quality protein [fresh meat/poultry/eggs/fish], low-glycaemic index, fresh fruit and vegetables and nuts, choosing low-fat over full-fat products, smoking cessation, minimising alcohol intake), with recipe, website, literature and other resource suggestions usually as part of a group discussion towards the last 5 minutes of each hour-long class.

Regarding safety of the intervention, classes will be small with a maximum of ten women per class, allowing one-to-one attention during classes. Intensity will be kept under control with the talk test, i.e. the subject can maintain a conversation during exercise, and in terms of the Borgs Rating of 12-14 (exertion of 65-75%). Measurement of physical activity will be documented by measuring the metabolic equivalent tasks (METs) as recommended by recent updated exercise in pregnancy guidelines (Zavorsky & Longo, 2011). In the information leaflet given to each woman at recruitment, participants will be informed of limitations, contraindications and warning signs while exercising.

Before commencing classes, each subject will have a counselling session with the research fellow and PI, Dr Daly. Individual counselling sessions have been found to be successful in terms of attendance in a feasibility study of a trial to prevent excessive pregnancy-related weight gain in Finland (Kinnunen et al., 2008). Resistance training within each class will be individualised following this consultation. During the individual counselling sessions the subject will be debriefed about her physical activity level, the level required, the means of how this could be achieved, and resistance training. Where participants are keen to engage in other forms of activity at a similar intensity, frequency and duration of these will be discussed with the research fellow, and the participant will be advised. Counselling will also take place regarding dietary and lifestyle choices, and the possibility and importance of change.

Each subject will undergo induction to the group classes through five fundamentals classes. This class is for beginners and takes subjects through nine basic functional movements essential to move safely in the exercise programme. Subjects learn to move correctly with minimal risk of injury.

Each subject is encouraged to attend three classes per week, and to log their class attendance and activity in a logbook for both personal and investigators ability to track progress within individual movements (repetitions, weights) and within workouts, and longitudinally over pregnancy. Outside the group class setting, women will be encouraged to increase their activity levels. In subjects found to engage in less than 10 minutes of exercise per day during the initial assessment, exercise will require longer and more frequent rest periods within the class.

The classes will be taught in the Education Centre of CWIUH. This means that any participant included in the study has already chosen to attend the hospital for antenatal care and thus, is most likely living or working in this catchment area, making access to the location simple. Classes will be offered at least twice per day and for at least four of five weekdays (8-15 classes to choose from per week, depending on the stage of the study and number of participants, invited to attend three per week). In order to facilitate attendance, we have taken measures to aid with childcare and compliance.
In terms of continuing this programme beyond the 6 weeks postpartum, after their participation in the study has ceased, these women will be referred to online resources to enable them to do classes in the comfort of their own homes (or with friends that they have made within the intervention group) should they so wish. These classes are already established internationally and are reproducible should any other unit wish to use this programme.

Standard antenatal care
Standard antenatal care for obese pregnant women is usually combined antenatal care between hospital and GP. With a BMI >29.9 kg/m2, they are ineligible for midwifery-led care. Visits are alternated until late pregnancy when all pregnancy visits are with an obstetrician in the hospital. As part of routine antenatal care, fasting bloods and Oral Glucose Tolerance Tests (OGTTs) are taken at 28 weeks to screen for gestational diabetes mellitus.

Fasting bloods will also be performed in all participants at 14 weeks gestation, 28 weeks gestation, 36 weeks gestation and 6 weeks postpartum to observe patterns and differences within and between the two groups.

A sample size of 28 per arm is required to have at least 80% power to detect a clinically meaningful difference of 0.4 mmol/L with a level of significance of 0.05.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 16/09/2014:
The primary purpose of this randomised controlled trial (RCT) is to determine if an intensive, supervised, established, sustained exercise intervention from early in the second trimester onwards would improve maternal glycaemic control in obese women. Specifically, we hypothesise that the exercise intervention will significantly decrease the mean maternal fasting glucose at 24-28 weeks gestation by 0.4 mmol per litre at the time of a standard 75 g OGTT to screen for gestational diabetes mellitus (HAPO, NEJM 2008) when compared with the mean maternal fasting glucose of the non-intervention group.

Previous primary outcome measures:
The primary purpose of this randomised controlled trial (RCT) is to determine if an intensive, supervised, established, sustained exercise intervention from early in the second trimester onwards would improve maternal glycaemic control in obese women. Specifically, we hypothesise that the exercise intervention will significantly decrease the mean maternal fasting glucose at 28 weeks gestation by 0.4 mmol per litre at the time of a standard 75 g OGTT to screen for gestational diabetes mellitus (HAPO, NEJM 2008) when compared with the mean maternal fasting glucose of the non-intervention group.

Secondary outcome measures
Current secondary outcome measures as of 16/09/2014:
The secondary objectives of the RCT will be to determine if the exercise programme in the intervention arm will improve significantly, when compared with non-intervention:

1. Gestational weight gain (GWG) in women at 24-28 weeks and 35-38 weeks gestation
2. Maternal weight retention at 6 weeks postpartum
3. Maternal body composition at 24-28 weeks and 35-38 weeks gestation and at 6 weeks postpartum
4. Objectively measured physical activity as measured by the IPAQ questionnaire at 24-28 and 35-38 weeks gestation and 6 weeks postpartum
5. Objectively measured physical activity as measured by RT6 accelerometer at 24-28 and 35-38

weeks gestation and at 6 weeks postpartum
6. Strength at 6 weeks postpartum
7. Fitness at 6 weeks postpartum
8. The number of abnormal OGTTs at 24-28 weeks gestation
9. The number of abnormal fasting lipid profiles
10. Insulin resistance measured at 24-28 weeks gestation
11. The inflammatory marker C-reactive protein as measured at 24-28 and 25-38 weeks gestation and 6 weeks postnatally
12. The white cell count as measured at 24-28 and 35-38 weeks gestation and at 6 weeks postpartum
13. Choice of food intake, as recorded on SLAN questionnaires at 24-28 and 35-38 weeks gestation and at 6 weeks postpartum
14. Quality of food intake as recorded on 7-day food and lifestyle diaries at 12-14, 24-28 and 35-38 weeks gestation and 6 weeks postpartum
15. Quality of life as measured by the EuroQOL questionnaire 6 weeks postpartum
16. The number of obstetric interventions (a composite measure of induction of labour and operative delivery)
17. The number of women requiring induction of labour
18. The number of women delivering before 37 weeks gestation
19. The number of women delivering after their expected due date
20. The number of caesarean deliveries
21. The length of the second stage of labour in minutes
22. Estimated fetal weight at 24-28 and 35-38 weeks gestation
23. Ultrasonographic markers of fetal adiposity
24. Birth weight
25. Body composition of the neonate
26. The number of cases of neonatal hypoglycaemia
27. The number of neonates requiring admission to the NICU for treatment of hypoglycaemia
28. The number of cases with cord-blood serum C-peptide level above the 90th centile

Note: The statistical powering of the RCT is based on the primary objective and not on the secondary objectives. The analysis may find statistical differences in the secondary objectives. However, if trends are identified of the impact of intervention, it may assist in powering future RCTs. The findings may also contribute to future meta-analysis.

Previous secondary outcome measures:
The secondary objectives of the RCT will be to determine if the exercise programme in the intervention arm will improve significantly, when compared with non-intervention:

1. Gestational weight gain (GWG) in women at 28 weeks and 36 weeks gestation
2. Maternal weight retention at 6 weeks postpartum
3. Maternal body composition at 28 weeks and 36 weeks gestation and at 6 weeks postpartum
4. Objectively measured physical activity as measured by the IPAQ questionnaire at 28 and 36 weeks gestation and 6 weeks postpartum
5. Objectively measured physical activity as measured by RT6 accelerometer at 28 and 36 weeks gestation and at 6 weeks postpartum
6. Strength at 6 weeks postpartum
7. Fitness at 6 weeks postpartum
8. The number of abnormal OGTTs at 28 weeks gestation
9. The number of abnormal fasting lipid profiles
10. Insulin resistance measured at 28 weeks gestation
11. The inflammatory marker C-reactive protein as measured at 28 and 36 weeks gestation and 6

weeks postnatally
12. The white cell count as measured at 28 and 36 weeks gestation and at 6 weeks postpartum
13. Choice of food intake, as recorded on SLAN questionnaires at 28 and 36 weeks gestation and at 6 weeks postpartum
14. Quality of food intake as recorded on 7-day food and lifestyle diaries at 12-14, 28 and 36 weeks gestation and 6 weeks postpartum
15. Quality of life as measured by the EuroQOL questionnaire 6 weeks postpartum
16. The number of obstetric interventions (a composite measure of induction of labour and operative delivery)
17. The number of women requiring induction of labour
18. The number of women delivering before 37 weeks gestation
19. The number of women delivering after their expected due date
20. The number of caesarean deliveries
21. The length of the second stage of labour in minutes
22. Estimated fetal weight at 28 and 36 weeks gestation
23. Ultrasonographic markers of fetal adiposity
24. Birth weight
25. Body composition of the neonate
26. The number of cases of neonatal hypoglycaemia
27. The number of neonates requiring admission to the NICU for treatment of hypoglycaemia
28. The number of cases with cord-blood serum C-peptide level above the 90th centile

Note: The statistical powering of the RCT is based on the primary objective and not on the secondary objectives. The analysis may find statistical differences in the secondary objectives. However, if trends are identified of the impact of intervention, it may assist in powering future RCTs. The findings may also contribute to future meta-analysis.

Overall study start date
07/10/2013

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Pregnant
2. BMI more 29.9 kg/m2 (obese)
3. Over 18 years of age
4. Fluent in English
5. Able to give written informed consent
6. Willing to be assigned to any of the intervention groups

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
304

Key exclusion criteria
Current exclusion criteria as of 16/09/2014:
1. BMI less than 29.9 kg/m2
2. Gestation >17 weeks gestation
3. Multiple pregnancy
4. Pre-existing diabetes mellitus
5. Hypertension (systolic pressure >160 mmHg and/or diastolic pressure >100 mmHg) or requiring antihypertensive medication
6. Alcohol abuse (i.e., two glasses alcohol or more per day)
7. Drug abuse (except for incidental analgesic agents)
8. Use of medication that affects insulin secretion or insulin sensitivity (antiviral, corticosteroids, antihypertensive drugs, all medication will be discussed)
9. Serious cardiorespiratory disorders
10. Hepatic or renal (serum creatinine >100 µmol/l) impairment
11. Systemic lupus erythematosus
12. Haematological disorders
13. Thalassaemia
14. Coeliac disease
15. Current psychosis
16. Malignant disease
17. Contraindications outlined on the parmed-x form

Previous exclusion criteria:
1. BMI less than 29.9 kg/m2
2. Multiple pregnancy
3. Pre-existing (gestational) diabetes mellitus
4. Hypertension (systolic pressure >160 mmHg and/or diastolic pressure >100 mmHg) or requiring antihypertensive medication
5. Alcohol abuse (i.e., two glasses alcohol or more per day)
6. Drug abuse (except for incidental analgesic agents)
7. Use of medication that affects insulin secretion or insulin sensitivity (antiviral, corticosteroids, antihypertensive drugs, all medication will be discussed)
8. Serious cardiorespiratory disorders
9. Hepatic or renal (serum creatinine >100 µmol/l) impairment
10. Systemic lupus erythematosus
11. Haematological disorders
12. Thalassaemia
13. Coeliac disease
14. Thyroid disease
15. Current psychosis
16. Malignant disease
17. Contraindications outlined on the parmed-x form

Date of first enrolment

19/11/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Coombe Women and Infants University Hospital
Dublin
Ireland
Dublin 8

Sponsor information

Organisation
Coombe Women and Infants University Hospital (Ireland)

Sponsor details
Cork Street
Dublin
Ireland
Dublin 8

Sponsor type
Hospital/treatment centre

Website
http://www.coombe.ie/

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Coombe Women and Infants University Hospital (Ireland)

Funder Name
University College Dublin (Ireland)

Alternative Name(s)
UCD

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/11/2017		Yes	No