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OptiMUM Nutrition: a web-based dietary intervention in pregnancy to optimise neonatal outcomes

Submission date
27/02/2016

Recruitment status
No longer recruiting

Registration date
04/03/2016

Overall study status
Completed

Last Edited
18/10/2017

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Nutrition during pregnancy plays a key role in providing the best environment for the baby's growth and development. If the baby is not provided with appropriate nutrition during pregnancy, they may be at increased risk of poor health later in life. This study aims to investigate if a web-based dietary intervention during pregnancy improves the health of the mother and the baby.

Who can participate?
Women aged over 18 who are in the first trimester of a single pregnancy.

What does the study involve?
Participants complete a number of questionnaires about their dietary, physical activity and lifestyle behaviours, and have their weight measured. They are then allocated at random to either the intervention group or the control group. The intervention group receive individualised dietary advice at regular intervals throughout the remainder of their pregnancy. This advice is delivered over the web. In addition, the intervention group receive information to promote positive behaviours such as exercise. Participants who are diagnosed with gestational diabetes are also provided with dietary and lifestyle advice in line with gestational diabetes guidelines. These participants' blood glucose and serum lipid measurements are collected. The control group re-take the dietary questionnaire over the course of their pregnancy, but instead of the individualised dietary advice provided to the intervention group, they receive standard care.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
October 2015 to October 2017

Who is funding the study?
Dublin Institute of Technology (Ireland)

Who is the main contact?
Dr Daniel McCartney

Contact information

Type(s)
Scientific

Contact name
Dr Daniel McCartney

Contact details
School of Biological Science
Dublin Institute of Technology
Kevin Street
Dublin
Ireland
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Additional identifiers

Study information

Scientific Title
OptiMUM Nutrition: a web-based dietary intervention in pregnancy to optimise neonatal outcomes

Acronym
OptiMUM

Study objectives
Current hypothesis as of 09/10/2017:
This study aims to establish whether access to a customised website providing evidence-based nutrition information from early pregnancy improves pregnancy outcomes.

Previous hypothesis:
This study aims to establish whether individualised online dietary advice to enhance maternal dietary intakes from early pregnancy yields improvements in neonatal health outcomes at birth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Coombe Women and Infants University Hospital’s Research Ethics Committee, ref: Study No. 6 – 2015
2. The Dublin Institute of Technology’s Research Ethics Committee, ref: 15-45

Primary study design
Interventional

Study design
Single-blinded randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy, gestational diabetes

Interventions
Current interventions as of 09/10/2017:
Participating mothers will be recruited using a convenience sampling method of a confirmed singleton pregnancy as per the inclusion criteria. Written consent will be obtained. Once recruited, women will complete a number of questionnaires to determine their current socio-economic status, attitudinal and psychometric parameters, and their dietary, physical activity and lifestyle behaviours. Women will also have their weight status measured at this point. Women will then be allocated at random to either the intervention group or the control group.
1. The intervention group will receive access to an evidence-based nutrition and lifestyle website in addition to standard care.
2. The control group will receive standard care alone.

Previous interventions:
Participating mothers will be recruited using a convenience sampling method in their first trimester of a confirmed singleton pregnancy as per the above inclusion criteria. Written consent will be obtained. Once recruited, women will complete a number of questionnaires to determine their current socio-economic status, attitudinal and psychometric parameters, and their dietary, physical activity and lifestyle behaviours. Women will also have their weight status measured at this point. Women will then be allocated at random to either the intervention group or the control group.
1. The intervention group will receive individualised dietary advice at regular intervals throughout the remainder of their pregnancy. This advice will be delivered over the web. In addition, the intervention group will receive information to promote positive lifestyle behaviours such as exercise. Consenting participants diagnosed with gestational diabetes will be sub-categorised within the intervention group and provided with dietary and lifestyle advice in line with gestational diabetes guidelines. These participants' blood glucose and serum lipid measurements will be collected.
2. The control group will re-take the dietary questionnaire over the course of their pregnancy, but instead of the individualised dietary advice provided to the intervention group, they will receive standard care alone.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 09/10/2017:
Birth weight, measured as part of standard antenatal and postnatal care

Previous primary outcome measures:
Neonatal weight and health status

Key secondary outcome(s)
Current secondary outcome measures as of 09/10/2017:
1. Maternal engagement with the website, measured using web-stat analytics from recruitment at baseline throughout the gestational period
2. Neonatal OFC, measured as part of standard antenatal and postnatal care
3. Maternal GDM diagnosis, measured as part of standard antenatal and postnatal care
4. Maternal mode of delivery, measured as part of standard antenatal and postnatal care
5. Neonatal mode of feeding, measured as part of standard antenatal and postnatal care

Previous secondary outcome measures:
1. Maternal weight
2. Maternal dietary intakes
3. Maternal dietary quality
4. Maternal blood glucose and serum lipids
5. Maternal dietary and lifestyle knowledge
6. Maternal psychometric measurements

Completion date
30/10/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/10/2017:
1. Women with a singleton pregnancy
2. Aged over 18
3. Have internet access
4. Proficient English
5. <18 weeks gestation

Previous inclusion criteria:
1. Women with a singleton pregnancy
2. Aged over 18
3. Have internet access
4. Proficient English
5. In their first trimester of pregnancy

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
Female

Key exclusion criteria
Women who do not meet the inclusion criteria

Date of first enrolment
01/10/2015

Date of final enrolment
30/10/2017

Locations

Countries of recruitment
Ireland

Study participating centre
The Coombe Women and Infants University Hospital
Ireland
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Sponsor information

Organisation
Dublin Institute of Technology (Ireland)

ROR
https://ror.org/04t0qbt32

Funder(s)

Funder type
University/education

Funder Name
Dublin Institute of Technology (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other