

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

<b>Submission date</b> 27/02/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/03/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/10/2017	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## 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

## **Study design**

Single-blinded randomised controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

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

## **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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/01/2015

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

500

**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)

**Sponsor details**

The School of Biological Sciences  
Dublin Institute of Technology  
Kevin Street  
Dublin  
Ireland  
0000

**Sponsor type**

University/education

**ROR**

<https://ror.org/04t0qbt32>

**Funder(s)****Funder type**

University/education

**Funder Name**

Dublin Institute of Technology (Ireland)

**Results and Publications****Publication and dissemination plan****Intention to publish date**

30/10/2017

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Other