

# Relationship between maternal egg intake and foetal development

**Submission date**  
14/08/2008

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
03/12/2008

**Overall study status**  
Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**  
15/12/2008

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Daniel Hoffman

**Contact details**  
Rutgers, The State University of New Jersey  
27 Nichol Avenue  
Room 228B  
New Brunswick  
United States of America  
08901

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

## Scientific Title

### Study objectives

Daily consumption of whole eggs during pregnancy promotes foetal growth and development in children born to low-income women.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Rutgers Human Subjects Investigational Review Board, approved on 20/05/2008
2. State University of Rio de Janeiro Human Subjects Ethics Board, approved in January 2008

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

### 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

Maternal nutrition and foetal development

### Interventions

The participants are allocated to four study arms:

Group 1: Normal dietary intake who never consume eggs (non-random allocation)

Group 2: Normal diet who are instructed not to consume eggs (random allocation)

Group 3: Normal diet who are instructed to eat at least one egg per day (random allocation).

They will be provided with vouchers redeemable at local stores for the purchase of eggs only.

Group 4: Control group (non-random allocation). They will be provided with standard dietary counselling for pregnant women.

Total duration of interventions: Three months

### Intervention Type

Drug

### Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

Eggs

**Primary outcome measure**

1. Foetal growth, measured at 3 months and 6 months of gestation
2. Newborn ponderal index, measured at birth
3. APGAR score, measured at birth

**Secondary outcome measures**

1. Maternal body composition, measured at 3 months of gestation
2. Newborn body composition, measured at birth

**Overall study start date**

01/09/2008

**Completion date**

01/09/2010

## **Eligibility**

**Key inclusion criteria**

1. Women between the ages of 18 and 40 years
2. Those who are in their 4th or 5th month of singleton pregnancy
3. Free from chronic diseases (heart disease, cancer, diabetes, hypertension, and other disorders that may influence metabolism and growth)
4. Reside in Duque de Caxias in Rio de Janeiro

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

400

**Key exclusion criteria**

1. Women who are beyond their 6th month of pregnancy
2. Pregnant with more than one foetus
3. Current use of tobacco, alcohol or illegal drugs
4. Younger than 18 or older than 40 years of age

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/09/2010

## **Locations**

**Countries of recruitment**

Brazil

United States of America

**Study participating centre**

**Rutgers, The State University of New Jersey**

New Brunswick

United States of America

08901

## **Sponsor information**

**Organisation**

Egg Nutrition Center (USA)

**Sponsor details**

1900 L Street NW Suite 725

Washington, DC

United States of America

20036

**Sponsor type**

Industry

**Website**

<http://www.enc-online.org>

**ROR**

<https://ror.org/00289h314>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Egg Nutrition Center (USA)

**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