

# Relationship between maternal egg intake and foetal development

<b>Submission date</b> 14/08/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/12/2008	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

## 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

**Study type(s)**

Prevention

**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(s)**

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

**Key secondary outcome(s)**

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

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

Female

## 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)

## ROR

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

# Funder(s)

## Funder type

Industry

## Funder Name

Egg Nutrition Center (USA)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration