

# The effect of a micronutrient rich food on Indian women's health and nutrient status

<b>Submission date</b> 16/06/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/07/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/10/2014	<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**  
Prof Caroline Fall

**Contact details**  
Medical Research Council - Epidemiology Resource Centre  
Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
A randomised controlled trial investigating the change in micronutrient status of Indian women as a result of consuming a micronutrient rich food

**Study objectives**

Daily consumption of a fruit based supplement over a three-month period will produce an improvement in the nutrient status and in functional health indicators measured in young Indian women.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Ethics Committee, Department of Pharmacology, Grant Medical College & Sir JJ Group of Hospitals, Mumbai, India, 07/10/2009, ref: No.IEC/Pharm/482/09

### **Study design**

Interventional single-centre randomised non-blinded controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Micronutrient deficiencies, functional health

### **Interventions**

The intervention is an experimental food consumed six days per week. The experimental food is a micronutrient rich snack weighing approx 65 g, (energy value: about 180 kcal) containing 20 g green leafy vegetables (e.g. spinach, coriander, amaranth), 10 g fruit (figs, dates, raisins) and 12 g dried milk powder. The control food contains foods of low micronutrient content including potato, tapioca and onion. All snacks contain spices and binding ingredients such as flour and resemble a samosa or patty. There are a variety of recipes in the intervention and control groups to prevent monotony.

Total duration of treatment: 12 weeks; at present no follow-up is planned. Final measurements will be taken at 12 weeks after the start of supplementation.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Serum retinol using high-performance liquid chromatography (HPLC)
2. Plasma vitamin C using HPLC
3. Serum folate and serum vitamin B12 using microbiological assays
4. Serum ferritin using enzyme-linked immunosorbent assay (ELISA) method

Samples taken at 0, 6 and 12 weeks after supplementation starts.

Added 13/10/2014:

5. Plasma and erythrocyte fatty acids, analysed using gas chromatography

6. Erythrocyte antioxidant enzyme SOD, analysed using enzyme-linked immunosorbent assay (ELISA) Cayman's kit
7. Erythrocyte antioxidant enzyme GPx, analysed using colorimeter
8. Plasma malondialdehyde, analysed spectrophotometrically

These outcomes were measured at baseline (0 week) and 12 weeks after supplementation started.

### **Key secondary outcome(s)**

1. Grip strength measured using a hand held dynamometer
2. Body composition by anthropometry
3. Changes in diet as a result of consumption of the snack measured using 3 x 24 hour recalls and a Food Frequency Questionnaire
4. Night blindness measured by questionnaire

Measurements made at 0 and 12 weeks after supplementation starts.

### **Completion date**

01/01/2010

## **Eligibility**

### **Key inclusion criteria**

1. Female
2. Aged 16 - 35 years
3. Living in the Ghatkopar area of Mumbai, India
4. Not pregnant
5. Not lactating
6. Willing to consume the snack food for 3 months

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

01/10/2009

### **Date of final enrolment**

01/01/2010

# Locations

## Countries of recruitment

United Kingdom

England

India

## Study participating centre

**Medical Research Council - Epidemiology Resource Centre**

Southampton

United Kingdom

SO16 6YD

# Sponsor information

## Organisation

Medical Research Council (MRC) (UK) - Epidemiology Resource Centre

## ROR

<https://ror.org/052578691>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council (MRC) (UK) - Epidemiology Resource Centre

## Funder Name

Centre for the Study of Social Change (India)

# Results and Publications

Individual participant data (IPD) sharing plan

## **IPD sharing plan summary**

Not provided at time of registration