

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

Submission date 16/06/2009	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 30/07/2009	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 13/10/2014	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

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Contact details

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Additional identifiers

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

Primary study design

Interventional

Study design

Interventional single-centre randomised non-blinded controlled trial

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

