

# Mumbai Maternal Nutrition Project

<b>Submission date</b> 11/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/03/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
074048

## Study information

**Scientific Title**  
Mumbai Maternal Diet Study: randomised controlled trial of micronutrient-dense food before and during pregnancy to prevent low birthweight

## **Acronym**

Project Saras

## **Study objectives**

Supplementation of women with a food-based micronutrient-rich supplement for at least three months prior to conception, and throughout pregnancy, will reduce the incidence of low birthweight, reduce infant mortality, and improve functional outcomes in the children, including growth, neuro-cognitive function and cardiovascular disease risk factors.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. UK: Southampton and South West Hampshire Local Research Ethics Committee, 13/01/2003, ref: 377/02/t
2. Mumbai: BYL Nair and TN Medical College Ethics Committee, 17/09/2002

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

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

Pregnancy outcome and infant mortality

## **Interventions**

Women who are not pregnant, but are planning to have further children, will be recruited and randomised to one of four groups, to receive one of two interventions: a daily food-based supplement made from vegetables, fruit, and milk, of differing micronutrient content. Supplementation will be supervised. Field staff will record menstrual dates, in order to detect pregnancy as early as possible. Women who become pregnant will have investigations during pregnancy, including blood samples and ultrasound scans.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

1. Birthweight
2. Infant mortality

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

1. Maternal micronutrient status
2. Maternal infection load and immune status
3. Foetal losses (miscarriages and stillbirths)
4. Newborn body composition
5. Newborn immune function

**Completion date**

31/03/2010

## Eligibility

**Key inclusion criteria**

1. Women living in slum communities in Bandra and Khar districts of Mumbai served by the Women of India Network (WIN) primary health care clinics
2. Women who wish to join
3. Married
4. Aged 15 to 35 years
5. Not pregnant at recruitment
6. Not using any PERMANENT form of contraception
7. Intending to have more children
8. Planning any future deliveries in Mumbai

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

6513

**Key exclusion criteria**

1. Women living outside the study area
2. Non-married women
3. Women outside the age range specified
4. Women currently pregnant (these may become eligible after delivery)
5. Women who have undergone sterilisation surgery, or whose husbands have had a vasectomy
6. Women definitely not planning further pregnancies
7. Women definitely planning further deliveries outside Mumbai

**Date of first enrolment**

09/01/2006

**Date of final enrolment**

30/06/2009

## Locations

**Countries of recruitment**

United Kingdom

England

India

**Study participating centre**  
**Southampton General Hospital**  
Southampton  
United Kingdom  
SO16 6YD

## Sponsor information

**Organisation**  
Centre for the Study of Social Change (India)

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Wellcome Trust

**Alternative Name(s)**

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
International organizations

**Location**  
United Kingdom

**Funder Name**  
Parthenon Trust, ICICI Ltd (Mumbai)

**Funder Name**

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2014		Yes	No
<a href="#">Results article</a>	results	01/07/2016		Yes	No
<a href="#">Results article</a>	results	01/07/2019	14/04/2020	Yes	No
<a href="#">Results article</a>	Follow up results	07/01/2022	12/01/2022	Yes	No
<a href="#">Results article</a>		18/02/2023	27/03/2023	Yes	No