

# Pilot study for a cluster randomized trial of community engagement interventions to increase immunization coverage among children 12-23 months of age in India

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| <b>Submission date</b><br>08/07/2015   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>14/07/2015 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>21/09/2015       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

### Background and study aims

We conducted a pilot study of participatory learning and community engagement interventions to improve vaccination coverage in children under 24 months of age in rural Uttar Pradesh, India. The study was designed to assess feasibility and improve methods for a future study of these interventions.

### Who can participate?

Women living in 12 villages in rural Uttar Pradesh who were mothers of a child 0 to 23 months of age.

### What does the study involve?

Villages were randomly allocated to either the intervention group or the control group. Over 4 months, the intervention group villages received home visits by volunteers and community mobilization events to promote immunization. The control group villages received community mobilization to promote nutrition. A toll-free number for immunization was offered to residents in both groups.

### What are the possible benefits and risks of participating?

Possible benefits include increased knowledge about child health (immunization and nutrition). We anticipated no specific risks to participation in the study.

### Where is the study run from?

Pratham Education Foundation - ASER Centre (India).

### When is the study starting and how long is it expected to run for?

January 2014 to June 2014.

Who is funding the study?

The Bill & Melinda Gates Foundation, the Canadian Institutes for Health Research and the Shastri Indo-Canadian Institute.

Who is the main contact?

Dr Mira Johri

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## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Participatory learning and community mobilization interventions versus usual care to increase immunization coverage among children 12-23 months of age in India: pilot study for a cluster randomized trial

### Study objectives

We hypothesized that delivery of participatory learning and community mobilization interventions to increase immunization coverage among children 12-23 months of age in India would be feasible.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Pratham Ethics Committee, B 4/54, Safdarjang Enclave, New Delhi, India, 10/12/2013
2. Research Ethics Committee of the University of Montreal Hospital Research Centre (CRCHUM), CE 12.391, 10/04/2013; updated 10/12/2013

**Study design**

Single-center intervention feasibility study using a cluster-randomized design

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Vaccine-preventable diseases in children (tuberculosis, polio, diphtheria, pertussis, tetanus, Hepatitis B, measles)

**Interventions**

Clusters were assigned to the intervention group (IG) or the control group (CG) using a computer-generated randomization schedule. Neither participants nor those delivering interventions were blinded, but those assessing outcomes were blinded to group assignment.

Over 4 months, IG villages received:

1. Home visits by volunteers
2. Community mobilization events to promote immunization

CG villages received community mobilization to promote nutrition.

A toll-free number for immunization was offered to all IG and CG village residents.

**Intervention Type**

Behavioural

**Primary outcome(s)**

Primary outcomes were ex-ante criteria for feasibility of the main study related to processes for recruitment and randomization (50% of villages would agree to participate and accept randomization; 30 women could be recruited in 70% of villages) and retention of participants (50% of women retained from baseline to end line).

**Key secondary outcome(s)**

We studied process indicators related to implementation fidelity and two indicators of community response. We also studied three proxy indicators of intervention impact on immunization uptake. We described differences between IG and CG villages for two cluster-level outcomes:

1. Use of the toll-free number
2. Monthly immunization day footfall
3. We compared performance of IG versus CG participants on the change from baseline to end line survey on key knowledge and awareness indicators.

**Completion date**

30/06/2014

# Eligibility

## Key inclusion criteria

Adult (18 years of age or older) females living in a study site who are mothers of a child 0-23 months of age

## Participant type(s)

Healthy volunteer

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

Female

## Key exclusion criteria

Unable to speak Hindi or Urdu

## Date of first enrolment

12/01/2014

## Date of final enrolment

03/02/2014

# Locations

## Countries of recruitment

India

## Study participating centre

Pratham Education Foundation - ASER Centre

B 4/54, Safdarjang Enclave

New Delhi

India

110029

# Sponsor information

**Organisation**

Centre de Recherche du Centre Hospitalier de l'Université de Montreal (CRCHUM)

**Organisation**

Pratham Education Foundation - ASER Centre

**Organisation**

Centre Hospitalier de l'Université de Montréal

**ROR**

<https://ror.org/0410a8y51>

**Funder(s)****Funder type**

Charity

**Funder Name**

Bill and Melinda Gates Foundation

**Alternative Name(s)**

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

**Funder Name**

Canadian Institutes of Health Research

**Alternative Name(s)**

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

**Funder Name**

Shastri Indo-Canadian Institute

**Alternative Name(s)**

Shastri Institute, Shastri Indo Canadian Institute, indo-canadien Shastri Institut, Institut indo-canadien Shastri, , - , SICI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

India

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 18/09/2015   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |