

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

Submission date 08/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/07/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/09/2015	Condition category 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?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet.

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 measure

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).

Secondary outcome measures

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.

Overall study start date

12/01/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

We sought to enroll 12 clusters and 36 participants per cluster, for a total of 432 participants allocated equally between intervention and control arms

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'Universite de Montreal (CRCHUM)

Sponsor details

850, rue St-Denis

Montreal

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info.cr.chum@ssss.gouv.qc.ca

Sponsor type

Hospital/treatment centre

Website

<http://crchum.chumontreal.qc.ca/>

Organisation

Pratham Education Foundation - ASER Centre

Sponsor details

B 4/54, Safdarjang Enclave

New Delhi

India

110029
+91 (0)114 602 3612
contact@asercentre.org

Sponsor type

Charity

Website

<http://www.asercentre.org/>

Organisation

Centre Hospitalier de l'Université de Montréal

Sponsor details

Sponsor type

Not defined

Website

<http://www.chumontreal.qc.ca/>

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, 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, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

Shastri Indo-Canadian Institute

Alternative Name(s)

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

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

India

Results and Publications

Publication and dissemination plan

We intend to publish the results of this trial in a high-impact peer-reviewed scientific journal.

Intention to publish date

01/08/2015

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?
Results article	results	18/09/2015		Yes	No