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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

Registration date
14/07/2015

Last Edited
21/09/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

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

Primary study design
Interventional

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

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'Universite 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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), 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, Institut indo-canadien Shastri, indo-canadien Shastri Institut, L'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?
Results article	results	18/09/2015		Yes	No