ISRCTN44840759 https://doi.org/10.1186/ISRCTN44840759

An mHealth intervention to improve vaccination uptake and other health outcomes among rural Indian children: pilot study for a cluster-randomized trial

Submission date
22/04/2018

Recruitment status
No longer recruiting

Registration date
02/05/2018

Overall study status
Completed

Last Edited
19/06/2023

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
The Government of India offers Village Health and Nutrition Days (VHNDs) to make health services and information accessible to underserved rural communities. VHNDs are designed to provide firstcontact primary health care to rural areas by bringing together a large package of basic health,
nutrition, and sanitation services offered free-of-charge in a single location each month. Core services include those for reproductive, maternal, new-born and child health, including immunisation, tuberculosis and HIV treatment and control, and counselling for communicable disease prevention and health promotion. Despite improvements, India's under-5 mortality rate (48 deaths per 1,000 live births) remains high, health knowledge is low, poor health behaviours are common, and only 62% of children are fully immunized. Research shows that many essential services designed to be offered by VHNDs are currently not reaching the population effectively. Building on the opportunity presented by widespread mobile phone ownership, we are piloting an interactive, voice-based, mobile platform (Tika Vaani, or "vaccine voice") to respond to this gap, with a focus on child health.
This study aims to conduct an evaluation with three objectives: (1) To assess the feasibility of processes key to the success of the main study; (2) To study intervention impact on additional factors relevant to successful delivery of the interventions at scale, measured at individual and cluster levels; (3) To identify potential barriers to success for the larger trial and take steps towards their mitigation.

Who can participate?
Participants in the baseline survey are primary caregivers (usually mothers) of children 0 to 12 months of age residing in a study village. All residents of intervention villages are eligible to participate in study interventions.

What does the study involve?
Participants from rural Indian villages receive an intervention that combines educational

capsules in entertaining formats (edutainment) broadcast via mobile phone and community mobilization activities consisting of a sequence of 4 meetings. Community meetings are conducted at convenient gathering points within villages. Those who listen via mobile phone do so at their convenience, generally in their own homes. All participants are offered the same intervention. The platform includes content on themes important for children's health immunization, nutrition, and water, sanitation and hygiene (WASH).
Over the same period, health workers receive early access to the same content and are invited to contribute to leading small group meetings, with the support of intervention field staff.

What are the possible benefits and risks of participating?
Participants have the opportunity to learn more about how to improve children's health. Participants will otherwise not gain any personal benefit from participating in this study. Apart from the time invested, there are no disadvantages or risks associated with participation in this study beyond those normally encountered in everyday life.

Where is the study run from?
Hardoi (India)

When is the study starting and how long is it expected to run for?
March 2015 to September 2018

Who is funding the study?
1. India-Canada Centre for Innovative Multidisciplinary Partnerships to Accelerate Community Transformation and Sustainability IC-IMPACTS (Canada)
2. Canadian Institutes for Health Research CIHR (Canada)
3. Grand Challenges Canada (GCC) (added 29/10/2019)

Who is the main contact?
Dr Mira Johri
mira.johri@umontreal.ca

Study website
http://www.tikavaani.org

Contact information

Type(s)
Scientific

Contact name
Prof Mira Johri

ORCID ID
http://orcid.org/0000-0001-5642-787X

Contact details
Centre de recherche du CHUM
Tour Saint-Antoine
Porte S03.414
850, rue St-Denis
Montreal

Canada
H2X 0A9

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20180422

Study information

Scientific Title
An mHealth intervention to improve vaccination uptake and other health outcomes among children 0 to 12 months of age in rural Uttar Pradesh, India: pilot study for a cluster-randomized trial

Study objectives
It is hypothesised that the main study would be feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Committee for Ethics and Review of Research Indian Institute of Health Management Research Jaipur 10/01/2017, no reference number
2. Comité d'éthique de la recherche du CHUM (Research ethics committee of the University of Montreal Hospital) 11/02/2017 ref:16.084

Study design
Pilot cluster-randomised intervention trial with a 1:1 allocation ratio

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

Not available in English, please use the contact details below to request a patient information sheet in Hindi

Health condition(s) or problem(s) studied
Child health

Interventions
The target populations reside in resource-poor rural areas with lagging health indicators, weak health services, and low levels of health knowledge and awareness. The study interventions offer social and behaviour change communication for members of the general public in rural Indian villages addressing topics related to child health. The primary target group is families residing in a selected village with a child in the age range 0 to 12 months; however, interventions are open to all village residents. The interventions include educational capsules in entertaining formats (edutainment) broadcast via mobile phone and community mobilisation.

The control group receive all standard health and welfare services offered by the Government of India. Most important among these are Village Health and Nutrition Days (VHNDs), which are designed to provide first-contact primary health care to rural areas by bringing together a large package of basic health, nutrition, and sanitation services offered free-of-charge in a single location each month. Core services include those for reproductive, maternal, new-born and child health, including immunisation, tuberculosis and HIV treatment and control, and counselling for communicable disease prevention and health promotion. Other programmes offered in the study area and designed to work synergistically with VHNDs include India's Integrated Child Development Services (ICDS) scheme, which offers nationwide nutrition and health promotion, the Janani Suraksha Yojana (JSY), a conditional cash transfer program launched in 2005 to reduce maternal and neonatal mortality by increasing births in health facilities, and Mission Indradhanush (MI), launched in 2014 to close existing vaccination coverage gaps through a focus on lagging areas and populations to ensure that all children will benefit from vaccination against seven vaccine preventable diseases by 2020.

In addition to these standard services, the intervention group receive:
General Public
• "Pushed" audio messages via mobile phone: Over a 3-month period, 13 information capsules and 13 short reminder messages with content in basic areas of importance to child health (Village Health & Nutrition Days, immunisation, water storage, hand washing, diarrhoea management and prevention, pneumonia management and prevention, dengue and chikungunya management and prevention), are "pushed" to consenting families with young children in the age range of 0-12 months. One new information capsule and one summary capsule of key points is pushed per week.. Timely reminder voice messages for immunisation is also pushed based on the child's birthdate and the GoI immunisation schedule. When a child's vaccination is due, families receive three calls (four days prior, one day prior, and on the day of the VHND (vaccination day)) informing them that the child's vaccinations are due and to go to the local vaccination centre. Other members of the general public in these villages are also eligible to receive pushed messages.
• "On-demand" access to content via mobile phone: Any person residing in an intervention village can phone the number to access content on demand through the IVR portal, to speak to an operator to facilitate linkage to content, or to leave a question or comment.
• Face-to-face community meetings: A sequence of 4 community meetings (1 large group introductory meeting, 3 small group meetings held at monthly intervals) are held in each intervention village. The introductory meeting invites the entire village with the purpose of informing the community about the intervention and encouraging participation. Small group

meetings focus on families with children in the target age range, but both large and small meetings are open to all. Each meeting in the series of 3 small group meetings is replicated several times per village to enable widespread participation. The number of replicates is established based on village size and knowledge of village social composition. Small group meetings are held separately for men and women to optimize ease of communication.

Health workers
• Over the same 3-month period, health workers receive early access to the same content and will be invited to contribute to leading small group meetings, with the support of intervention field staff. The goal is to build the capacity of health workers and to support them in their role. Interventions address individuals, households, and communities. While the primary focus of activities is on the child's primary caregiver (usually the mother), fathers and other family members are encouraged to participate. To facilitate community engagement and mobilization, intervention components will be accessible to all community members. All intervention components are available free of charge to end users.

Intervention Type
Behavioural

Primary outcome measure
The primary aim of this pilot study is to assess the feasibility of the planned main study. We will view the study as feasible if the following ex-ante criteria are met:
1. Recruitment and randomisation are feasible if: (i) 70% of villages approached agree to participate and accept randomisation; (ii) in participating villages, 70% of households with children in the target age range agree to participate and accept randomisation. Criteria related to recruitment and randomisation are assessed using data collected from project administrative records at study baseline (Week 0).
2. Interventions are feasible if uptake is sufficient to demonstrate acceptability and potential for impact, quantified as: 50% of households recruited to the study participate in interventions in some form (by listening to one or more outbound calls at home, and/ or by placing one or more calls, and/ or by attending community meetings). Participation in interventions was measured through two sources: (1) Call data were measured continuously throughout the study using the Tika Vaani interactive voice-response (IVR) system; (2) participation in community meetings was measured at community meetings taking place at Weeks 0, 4, 8, and 12.
3. Retention is feasible if 50% of households participating in the baseline survey agree to participate in the end line survey. This is assessed using data collected from project administrative records at study baseline (Week 0) and end line (after Week 13).
4. The design is feasible if the contamination proportion is below 15%. Contamination is assessed continuously throughout the study using the Tika Vaani interactive voice-response (IVR) system to identify the proportion of calls from callers outside the intervention group (i.e. control group villages, or non-study villages). The IVR system is used to identify unknown numbers and a moderator follows up on calls from non-registered callers to identify call origin. A contamination proportion in excess of 15% is a threat to the feasibility of using a cluster-randomised design with village as the unit of randomisation and geographical distances between villages similar to those in the pilot study.

Secondary outcome measures
1. Implementation fidelity is assessed by evaluating: (i) whether the activities are implemented as planned (content), (ii) whether the number of planned activities and the selected territory are respected (coverage) and (iii) if the planned frequency and duration of the activities are respected (frequency and duration). We will also explore whether there are specific moderating

factors that can explain the degree of fidelity obtained. Implementation fidelity is assessed using 5 data sources: (1) structured observation with a checklist used by each field worker to verify if planned activities are implemented as specified in terms of content, coverage, duration and frequency, continuously throughout the study; (2) semi-structured interviews with field workers involved in intervention delivery at study end line (after week 13); (3) surveys administered via mobile phone (open for completion continuously from Week 7 to Week 13); (4) semi-structured interviews with health workers and local government officials at study end line (after week 13); (5) Analysis of project documents and IVR metadata collected continuously throughout the study.
2. Acceptability, accessibility, and satisfaction of the interventions to end users is assessed using 3 data sources: baseline and end line surveys (administered at Week 0 and following Week 13), mobile phone surveys administered through the IVR (open for completion continuously from Week 7 to Week 13), and qualitative interviews (community meetings taking place at Weeks 0, 4, 8, and 12, and semi-structured exit interviews and group discussions administered after Week 13 following the end line survey).
3. Knowledge, attitudes, practices, and behaviours of end users related to child health themes addressed by the intervention are assessed using 2 data sources: baseline and end line surveys (administered at Week 0 and following Week 13), and qualitative interviews (exit interviews, group discussions) administered after Week 13 following the end line survey.
4. Community-level indicators (numbers and characteristics of participants in community events in intervention villages, numbers and characteristics of callers outside of the target group who use the IVR system in intervention villages, and numbers and characteristics of additional participants who join the end line survey in intervention and control villages) are captured continuously from the project administrative records and IVR platform. We also access administrative records of the Assistant Nurse Midwife (ANM) to identify the numbers of children vaccinated per immunisation centre in intervention and control villages over the study period, using data collected retrospectively after Week 13 following the endline survey.

Overall study start date
01/03/2015

Completion date
06/09/2018

Eligibility

Key inclusion criteria
Inclusion criteria for clusters (villages):
1. Have less than 4000 inhabitants
2. Located in Bawan Block, Hardoi district, UP.

Inclusion criteria for participants:
1. Baseline/endline: Primary caregivers (usually mothers) of children 0 to 12 months of age residing in a study village.
2. Survey: Households containing a child in the age range 0-12 months.
3. Interventions: resident of selected villages.

Participant type(s)
Healthy volunteer

Age group

Adult

Sex
Both

Target number of participants
Although the pilot study is a cluster randomised two-group study with a 1:1 ratio, the main outcome of interest from the perspective of sample size assessment related to the rate of contamination in the control group. We therefore estimated the required sample size for the study based on the size needed for the control group, using methods for sample size calculation in a one group descriptive study based on calculation of a confidence interval for a proportion. We assumed that the true proportion of contamination (calls originating from the control group) was 10%, that contamination was most likely to arise from parents of young children similar to those in the target group for the intervention, and that there would be 20 households with children less than 12 months of age per village (a conservative estimate based on census data). Based on these inputs and using a binomial ("exact") calculation, we would require 200 households in the control group to be able to detect a 95% confidence interval of 6.2% to 15.0%. 12,13 The total sample size for the study was therefore set at double this number, or 400 households (20 villages with 20 households with children less than 12 months of age per village). No assumptions were made about the clustering of contamination by village.

Total final enrolment
391

Key exclusion criteria
1. Not able to understand and speak Hindi or Urdu
2. Do not intend to reside in the village for the study duration (6 months)

Date of first enrolment
19/01/2018

Date of final enrolment
18/02/2018

Locations

Countries of recruitment
India

Study participating centre
Rural villages
Azad Nagar Grameen
Hardoi
India
241001

Sponsor information

Organisation
Centre de recherche du Centre Hospitalier de l'Université de Montréal

Sponsor details
Tour Saint-Antoine
Porte S03.414
850, rue St-Denis
Montreal
Canada
H2X 0A9

Sponsor type
University/education

Website
http://crchum.chumontreal.qc.ca/

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Government

Funder Name
The India-Canada Centre for Innovative Multidisciplinary Partnerships to Accelerate Community Transformation and Sustainability (IC-IMPACTS)

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
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/09/2020	22/09/2020	Yes	No
Results article	results	08/10/2020	13/10/2020	Yes	No
Participant information sheet	Informed consent		19/06/2023	No	Yes