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The impact of mobile voice messaging services in improving maternal, neonatal and child health

Submission date
15/08/2018

Recruitment status
No longer recruiting

Registration date
06/09/2018

Overall study status
Completed

Last Edited
04/06/2020

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
With the increasing use and ownership of mobile phones in developing countries, mHealth (the use of mobile phones in medical care) is being looked upon as an important tool to impact health outcomes such as in HIV care and treatment. In maternal, newborn and child health (MNCH) services, text messages have been more widely used than voice messages to deliver mHealth services. Text messages have been used effectively for improving attendance and adherence to antenatal and postnatal care advice, resulting in a substantial increase in clients attending clinics. Additionally, text messages have been used to inform women about care needed during pregnancy, delivery preparedness, immunisation schedules and good breastfeeding practices. mHealth has tremendous potential to reach pregnant women, especially poor women who are more difficult to reach with traditional communication channels such as television, radio and newspapers. mHealth can reach targeted clients more frequently, resulting in better results than is feasible for the traditional media. This study aims to improve the health and wellbeing of pregnant women and their newborns and infants through age and stage-based messages delivered via mobile phone, through a program called mMitra.

Who can participate?
Pregnant women aged 18 or older, who can speak Hindi or Marathi, have access to a mobile phone at home and are likely to be in Mumbai for 4-5 months during the pregnancy and post-delivery period

What does the study involve?
Women will be randomly allocated to either the intervention or the control group. Both groups will have access to standard information and services, including community health workers and health providers, and TV, radio and posters. Women in the intervention group will also have access to mMitra voice messages with information around 2 times per week throughout pregnancy and until their child turns 1 year of age.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. They will be given a small gift as a gesture of our appreciation for participating in this study. The information they provide will help us to understand how to improve health information delivery so women improve their own and their

babies' health. All the women will receive routine health benefits from the health system. There are no known risks to participants taking part in the study.

Where is the study run from?
1. F North Ward, Mumbai (India)
2. N East Ward, Mumbai (India)

When is the study starting and how long is it expected to run for?
March 2015 to January 2017

Who is funding the study?
Johnson & Johnson (USA)

Who is the main contact?
Dr Nirmala Murthy

Contact information

Type(s)
Scientific

Contact name
Dr Prakash Muthuperumal

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol No. HHS00009235

Study information

Scientific Title
Mobile Health Technology Evaluation: Assessing mMitra impact on health outcomes

Acronym
mMitra

Study objectives
The mobile messaging (mMitra) program will lead to improved:
1. Mother and infant care knowledge
2. Pregnancy and infant care practices
3. Maternal and infant health outcomes such as lower incidence of anemia during pregnancy, increased birth weight of newborn and decrease under-nutrition among infants

Ethics approval required
Old ethics approval format

Ethics approval(s)
Foundation for Research in Health Systems (FRHS) IRB, 30/12/2014, Protocol No. HHS00009235.

Study design
Interventional prospective cohort randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please contact admin@frhsindia.org for a participant information sheet

Health condition(s) or problem(s) studied
Maternal, neonatal and infant care knowledge and practice

Interventions
This study was designed as a randomised controlled trial in which a specified number of pregnant women from urban slum areas of Mumbai were enrolled in the study. These women were randomly assigned to the intervention and control groups to receive or not to receive

mMitra messages and were followed until their newborns became one year of age. Prior to initiating the trial, baseline data was gathered from the women on selected awareness, behaviour, and the health outcome indicators that mMitra was seeking to improve. Three interviews were conducted with the same women, firstly at the baseline, and then within 2-3 weeks of childbirth and when the child turns one year of age. Both the control and intervention groups will have access to common sources of information, including community health workers and health providers, along with mass media such as TV, radio and posters. Women in the intervention arm also have access to mMitra messages, in addition to the other sources. Women in this group will receive voice messages at an average frequency of twice per week throughout pregnancy and until the infant turns 1 year old.

Intervention Type
Device

Primary outcome measure
1. Reduction in anaemia (haemoglobin levels) during pregnancy, assessed using a review of records (MCH card) at the baseline, during each antenatal care (ANC) visit and immediately after delivery
2. Nutritional status of child (weight for age) at birth and after 12 months. Birth weight is recorded for each child immediately after delivery. This is assessed by a review of records (MCH card) and is self-reported by mothers during an interview.

Secondary outcome measures
1. Number of antenatal care (ANC) visits, assessed through an interview with the mother following delivery
2. Number of tetanus toxoid (TT) injections provided during pregnancy, assessed through an interview with the mother following delivery
3. Weight of women at ANC visits, assessed through an interview with the mother following delivery
4. Knowledge and awareness of pregnant women about the following, assessed through interviews with the mother and review of records (MCH card) at the baseline, after 2-3 weeks of childbirth and after 1 year:
4.1. Number of ANC visits
4.2. TT injections needed
4.3. Importance of colostrum
4.4. Breastfeeding practices
4.5. Routine monitoring of the weight of the baby
4.6. Supplementary foods

Overall study start date
01/03/2015

Completion date
15/01/2017

Eligibility

Key inclusion criteria

1. Pregnant women
2. Aged 18 years or older
3. Able to speak Hindi or Marathi
4. Access to a mobile phone at home

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
2000

Total final enrolment
2016

Key exclusion criteria
Unlikely to be in the same city for 4-5 months during the pregnancy and post-delivery period

Date of first enrolment
01/06/2015

Date of final enrolment
30/10/2015

Locations

Countries of recruitment
India

Study participating centre
F North and M East ward of Mumbai
1.Near Maheshwari Circle, Matunga East, Mumbai, Maharashtra 400019
Mumbai
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Sponsor information

Organisation
FRHS

Sponsor details
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Sponsor type
Research organisation

Website
http://www.frhsindia.org/index.html

ROR
https://ror.org/01cey1344

Funder(s)

Funder type
Not defined

Funder Name
Johnson and Johnson

Alternative Name(s)
Johnson & Johnson, johnson & Johnson Services, Inc., Johnson&Johnson, , Johnson & Johnson Private Limited, , J&J, JNJ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan

We have prepared three papers for publication:
1. "New Methodological Frontiers in Assessing mHealth Maternal and Child Health Outcomes: Challenges and Opportunities", which we intend to publish in the Maternal and Child Health Journal
2. "mHealth voice message service (mMitra) impact on infant care knowledge and practices among low-income women in India: findings from a prospective cohort controlled trial", which we intend to publish in a high-impact, peer-reviewed journal
3. "mHealth voice message service (mMitra) impact on infant care knowledge and practices among low-income women in India: findings from a randomized control trial", which we intend to publish in a high-impact, peer-reviewed journal

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
Individual data will be available without identifiers (e.g. name, location) as per the ethical committee approval, based on requests raised to admin@frhsindia.org. The data will be available by end of October 2018 for researchers and students for learning purposes only, as a soft copy. Publications, if any, to be done using this data should get prior permission from FRHS. Individual women have provided consent to participate in this study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	08/11/2019	Yes	No
Results article	results	01/06/2020	04/06/2020	Yes	No