ISRCTN25743783 https://doi.org/10.1186/ISRCTN25743783

Saving maternal and infant lives with affordable technology

Submission date
23/01/2017

Recruitment status
No longer recruiting

Registration date
31/01/2017

Overall study status
Completed

Last Edited
27/01/2020

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pakistan has one of the highest rates of maternal and infant deaths in the world. A possible reason for this may be that fewer than half of these women have a skilled birth attendant, such as a doctor or midwife, present when they are giving birth. Health surveys in Pakistan have shown that around 18 percent of pregnant women develop complications in pregnancy. Complications can lead to a higher risk of illness or death of the mother and/or baby, and the presence of skilled birth attendance (SBA) is the best way of minimizing these risks. Using mobile phone voice messages (telemessaging) to provide information about the importance of SBA, as well as how women should look after themselves and their baby during pregnancy and after they have given birth could help to improve survival rates. The aim of this study is to look at the effectiveness of a telemessaging service to help improve maternal and infant health outcomes.

Who can participate?
Women in their first trimester of pregnancy living within participating areas in Pakistan.

What does the study involve?
Participating women are randomly allocated to one of five groups. Those in the first four groups receive telemessaging, which provides information about using health services, nutrition, signs of pregnancy complications to look out for and vaccination. Those in the first group receive two messages per week timed with stages of pregnancy and after giving birth, those in the second group receive one message per week without any particular timing, those in the third group receive one message per week but without timing with stages of pregnancy and after giving birth, and those in the fourth group receive one message per week plus phone balance transfers if additional information is accessed. Those in the fifth group receive traditional health communication which does not involve receiving extra voice messages. At the start of the study and after 12 months, participants complete a survey and have their medical records reviewed to see what healthcare services they have used.

What are the possible benefits and risks of participating?
Women who receive the messages benefit from receiving information and guidance during their pregnancy which could help lower the risk of death or illness for themselves and their new baby's. There are no notable risks involved with participating.

Where is the study run from?
The study is run from King Edward Medical University and takes place in randomly chosen areas within 10 unions of 2 districts (Pakistan)

When is the study starting and how long is it expected to run for?
August 2014 to February 2018

Who is funding the study?
National Academy of Sciences (USA)

Who is the main contact?
Dr Musharraf Cyan
cyan@gsu.edu

Contact information

Type(s)
Public

Contact name
Dr Musharraf Cyan

Contact details
Georgia State University
Andrew Young School of Policy Studies
International Center for Public Policy
14 Marietta Street
Atlanta
United States of America
30300
+1 404 413 0244
cyan@gsu.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H14050

Study information

Scientific Title
Affordable technology to serve rural women across literacy barriers to save maternal and infant lives

Study objectives
The aim of this study is to test whether health messages linked to progression through pregnancy and six months postpartum that are delivered in female voices directly to the pregnant woman by cellphone have a statistically significant effect on maternal and infant mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Susan Laury Experimental Economics Center, Shelia L. White Office of Research Integrity, Georgia State University, 06/02/2015, ref: 331936

Study design
Cluster randomised trial

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 patient information sheet

Health condition(s) or problem(s) studied
Preventable maternal and infant mortality that occurs because of complications during pregnancy.

Interventions
Current intervention as of 27/01/2020:
Discrepancies in the protocol and registry were corrected with a protocol revision submitted to our IRB on 1-05-14. In the final tally, our subjects received a total of 110 messages (52 before delivery; 52 after delivery; 6 based on symptoms and complications.
372 participating villages of 2 districts of Pakistan are randomized to one of five groups. Women in the first trimester of pregnancy are recruited through a house to house survey for participation in the study. Participation is voluntary and is obtained using approved and standard informed consent procedures.
Intervention group 1: Women receive two telemessages per week timed with pregnancy and

infant care stages.
Intervention group 2: Women receive one telemessage per week timed with pregnancy and infant care stages.
Intervention group 3: Women receive one telemessage per week without any particular timing with pregnancy and postpartum stages but in random order to mimic public media messages.
Intervention group 4: Women receive one telemessage per week timed with pregnancy and infant care stages plus phone balance transfers if additional information accessed.
Control group: Women receive traditional health communication only.
In all groups, the treatment is applied over a period of 18 months. For the intervention groups, the telemessaging includes general and specific guidance on hygiene and maternal and infant nutrition, nutritional supplements, use of antenatal care and why and when necessary, monthly pregnancy checklists for the age of pregnancy, recognition of signs of pregnancy complications (especially pre-eclampsia and eclampsia), vaccination.
At baseline and after 18 months, a survey is carried out to record hygiene and nutrition practices, use of antenatal care, skilled birth attendance and postnatal care. The survey also inquires about households health outcomes especially those of the mother and the infant.

Previous intervention as of 20/01/2020:
411 participating villages of 2 districts of Pakistan are randomised to one of five groups. Women in the first trimester of pregnancy are recruited through a house to house survey for participation in the study. Participation is voluntary and is obtained using approved and standard informed consent procedures.

Intervention group 1: Women receive two telemessages per week timed with pregnancy and infant care stages.
Intervention group 2: Women receive one telemessage per week timed with pregnancy and infant care stages.
Intervention group 3: Women receive one telemessage per week without any particular timing with pregnancy and postpartum stages but in random order to mimic public media messages.
Intervention group 4: Women receive one telemessage per week timed with pregnancy and infant care stages plus phone balance transfers if additional information accessed.
Control group: Women receive traditional health communication only.

Intervention group 4: Women receive telemessaging with 78 timed messages plus phone balance transfers if additional information accessed.
Control group: Women receive traditional health communication only.

In all groups, the treatment is applied over a period of 18 months. For the intervention groups, the telemessaging includes general and specific guidance on hygiene and maternal and infant nutrition, nutritional supplements, use of antenatal care and why and when necessary, monthly pregnancy checklists for the age of pregnancy, recognition of signs of pregnancy complications (especially pre-eclampsia and eclampsia), vaccination.

At baseline and after 18 months, a survey is carried out to record hygiene and nutrition practices, use of antenatal care, skilled birth attendance and postnatal care. The survey also inquires about households health outcomes especially those of the mother and the infant.

Previous intervention:
411 participating villages of 2 districts of Pakistan are randomised to one of five groups. Women in the first trimester of pregnancy are recruited through a house to house survey for participation in the study. Participation is voluntary and is obtained using approved and standard informed consent procedures.

Intervention group 1: Women receive telemessaging with frequency of 130 messages timed with pregnancy and infant care stages.
Intervention group 2: Women receive telemessaging with frequency of 78 messages time with pregnancy and infant care stages.
Intervention group 3: Women receive telemessaging with frequency of 78 messages not timed with pregnancy and postpartum stages but in random oder to mimic public media messages.
Intervention group 4: Women receive telemessaging with 78 timed messages plus phone balance transfers if additional information accessed.
Control group: Women receive traditional health communication only.

In all groups, the treatment is applied over a period of 18 months. For the intervention groups, the telemessaging includes general and specific guidance on hygiene and maternal and infant nutrition, nutritional supplements, use of antenatal care and why and when necessary, monthly pregnancy checklists for the age of pregnancy, recognition of signs of pregnancy complications (especially pre-eclampsia and eclampsia), vaccination.

At baseline and after 18 months, a survey is carried out to record hygiene and nutrition practices, use of antenatal care, skilled birth attendance and postnatal care. The survey also inquires about households health outcomes especially those of the mother and the infant.

Intervention Type
Supplement

Primary outcome measure
Adoption of skilled birth attendance is measured using a survey designed for the purpose of this study and reviewing clinical notes at baseline and 18 months.

Secondary outcome measures
1. Adoption of specialist care upon referral is measured using a survey designed for the purpose of this study and reviewing clinical notes at baseline and 18 months
2. Gains in health literacy is measured using a survey designed for the purpose of this study and reviewing clinical notes at baseline and 18 months
3. Vaccination rates of infants at 12 months of age is measured using a survey designed for the purpose of this study and reviewing clinical notes at baseline and 18 months

Overall study start date
01/08/2014

Completion date
03/02/2018

Eligibility

Key inclusion criteria
1. Pregnant women
2. In the first trimester of pregnancy
3. Within the randomly chosen areas within 10 unions of 2 districts of Pakistan

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1556

Key exclusion criteria
1. In the second or third trimester of pregnancy
2. Non-pregnant women

Date of first enrolment
01/05/2015

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
Pakistan

Study participating centre
King Edward Medical University
Nelagumbad
Mayo Hospital Road
Lahore
Pakistan
54000

Sponsor information

Organisation
Georgia State University

Sponsor details
33 Gilmer St SE
Atlanta
United States of America
30302

Sponsor type

University/education

Website
http://www.gsu.edu

Organisation
King Edward Medical University

Sponsor details
Nelagumbad
Mayo Hospital Road
Lahore
Pakistan
54000
+92 42 99211145
info@kemu.edu.pk

Sponsor type
University/education

Website
http://kemu.edu.pk

Organisation
Georgia State University

Sponsor details

Sponsor type
Not defined

Website
http://www.gsu.edu/

ROR
https://ror.org/03qt6ba18

Funder(s)

Funder type
Charity

Funder Name

National Academy of Sciences

Alternative Name(s)
U.S. National Academy of Sciences, NatlAcad of Sciences, United States, National Academy of Sciences, The National Academy of Sciences, The U.S. National Academy of Sciences, NAS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 6 months.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Musharraf Cyan (cyan@gsu.edu)

IPD sharing plan summary
Available on request