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Video edutainment at the doorstep: impact on maternal and infant outcomes in Toro local authority in Bauchi state, Nigeria

Submission date
06/08/2017

Recruitment status
No longer recruiting

Registration date
11/08/2017

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Pregnant women attend health facilities to receive conventional antenatal care, but women at highest risk of morbidity (illness) and mortality (death) are least able to attend. Typically, they are socially isolated, overworked, poor, subject to gender violence and poorly educated. Nigeria has one of the highest rates of maternal mortality in the world, estimated as 576 deaths per 100,000 live births nationally and higher in Bauchi state. The Nigerian government has identified maternal mortality as a priority issue. Previous work in Bauchi state found four key links with negative outcomes of pregnancy: domestic violence, heavy work, lack of knowledge of danger signs, and lack of spousal communication about pregnancy. This study aims to answer the following questions:
1. Are universal home visits to pregnant women feasible and acceptable in northern Nigeria and what is their impact on pregnancy outcomes for mothers and babies?
2. How does adding video edutainment affect the feasibility and impact on pregnancy outcomes for mother and child?
3. In what way do home visits have an impact on pregnancy outcomes?

Who can participate?
Women of childbearing age (aged 14-49) living in six wards of Toro Local Government Authority (LGA) who are pregnant or who become pregnant during the study

What does the study involve?
The study tests the impact on mothers' health of visiting all pregnant women every two months during their pregnancy and after delivery. In the visits, the female visitors ask them some questions about their health and discuss with them evidence about some problems that affect the outcome of pregnancy, and that can be tackled within the household: domestic violence, heavy work during pregnancy, lack of knowledge about danger signs of pregnancy, and lack of communication about pregnancy between women and their partners. Male workers visit the partners of the pregnant women to have the same discussions. The home visitors advise women with danger signs in their pregnancy to visit a health facility and provide a referral note for them. In half of the wards, the home visitors also show video clips to help the discussions about

the problems that affect pregnancy outcomes. By the end of the study, all six wards have home visits in place. During the study, wards with home visits in place are compared with wards with home visits not yet in place. This includes comparing the number of deaths of mothers in visited and unvisited wards.

What are the possible benefits and risks of participating?
The intention of the home visits is to improve the health of pregnant women and their unborn children. The potential benefit of participating is a healthier pregnancy and a healthier baby. No risks are anticipated.

Where is the study run from?
Researchers from the department of Family Medicine at McGill University, Montreal, Canada, working in collaboration with staff of the Federation of Muslim Women Association of Nigeria (FOMWAN) in Bauchi, together with the Primary Health Care Development Agency (PHCDA) of the Ministry of Health, Bauchi State, Nigeria

When is the study starting and how long is it expected to run for?
August 2015 to May 2020

Who is funding the study?
The study is supported under the IMCHA programme (Innovating for Maternal and Child Health in Africa) with funding from the International Development Research Centre (IDRC) in Canada, Canadian Institutes for Health Research (CIHR) and Global Affairs Canada (GAC)

Who is the main contact?
Dr Anne Cockcroft

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
108039-001 and 108039-002

Study information

Scientific Title
Video edutainment at the doorstep: impact on maternal and infant outcomes in Toro local authority in Bauchi state, Nigeria: a stepped wedge cluster randomised controlled trial

Study objectives
1. Are universal home visits feasible, acceptable and appropriate in areas of northern Nigeria other than Giade?
2. How does adding evidence-based video edutainment affect the feasibility, impact on maternal /infant outcomes, and cost of universal home visits?
3. What is the mechanism of impact of home visits on maternal outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Government of Bauchi State, Ministry of Health, 12/05/2015, ref: NREC/12/05/2015/12
2. McGill University, Faculty of Medicine IRB, 23/06/2015, ref: A06-B35-15A

Study design
Cluster randomised controlled trial in stepped wedge 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Maternal and infant morbidity and mortailty

Interventions
Six wards in Toro Local Government Authority (LGA) in Bauchi State, Nigeria, are randomly allocated (allocation by statistician outside the local study team) to three waves of two wards. The study uses central, computer based randomisation by an epidemiologist not associated with

the fieldwork. The randomisation is of whole districts, into intervention waves of 5 districts each, rather than randomisation of individuals. The duration of the intervention is three years. At this point, the primary and secondary outcomes will be measured in the five first wave (intervention) districts and in the five second wave districts, serving as the controls for the first wave districts.

The “treatment” is a package of structural interventions implemented in the five districts allocated to the first wave. The study tests the impact on mothers’ health of visiting all pregnant women every two months during their pregnancy and after delivery. In the visits, the female visitors ask them some questions about their health and discuss with them evidence about some problems that affect the outcome of pregnancy, and that can be tackled within the household: domestic violence, heavy work during pregnancy, lack of knowledge about danger signs of pregnancy, and lack of communication about pregnancy between women and their partners. Male workers visit the partners of the pregnant women to have the same discussions. The home visitors advise women with danger signs in their pregnancy to visit a health facility and provide a referral note for them. In half of the wards, the home visitors also show video clips to help the discussions about the problems that affect pregnancy outcomes.

Intervention Type
Behavioural

Primary outcome measure
Measured using a household cluster survey after 3 years:
1. Maternal morbidity
2. Maternal mortality
3. Infant morbidity

Secondary outcome measures
1. Items in the CASCADA model of Conscious knowledge, Attitudes, Subjective norms, intention to Change, Agency, Discussion and Action, measured using a questionnaire administered in the household survey after 3 years
2. Feasibiity and acceptability of the home visits, assessed using household cluster survey after 3 years

Overall study start date
24/08/2015

Completion date
23/05/2020

Eligibility

Key inclusion criteria
1. All women of childbearing age living in the trial intervention wards
2. Women in the above category who become pregnant are registered and visited 2-monthly during pregnancy and after delivery
3. Spouses of the pregnant women are also visited

Participant type(s)
Other

Age group

Adult

Sex
Both

Target number of participants
Approximately 18,000 pregnant women in the six wards covered during the trial

Total final enrolment
26413

Key exclusion criteria
Severe mental health problems making the person unable to give informed consent to participate and unable to respond to the administered questionnaire

Date of first enrolment
01/03/2016

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Nigeria

Study participating centre
Bauchi State Ministry of Health, Primary Health Care Development Agency
Bauchi
Nigeria
PMB 065, Bauchi

Sponsor information

Organisation
McGill University

Sponsor details
Department of Family Medicine
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Sponsor type
University/education

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Government

Funder Name
International Development Research Centre

Alternative Name(s)
Centre de recherches pour le développement international, IDRC, CRDI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

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

Results and Publications

Publication and dissemination plan
The study protocol is not yet published but the trialists intend to publish it. Planned publication of the results in a high-impact peer reviewed journal by the end of 2019.

Updated 09/04/2019:
The study protocol has now been published (see below).

Updated 04/06/2021:
Protocol and results published and further publications in review.

Intention to publish date
09/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during the study are not expected to be made available because the researchers did not seek agreement of the participants to make their data generally available for analysis by third parties.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/07/2018		Yes	No
Interim results article	interim results	08/02/2019	09/04/2019	Yes	No
Results article		01/02/2021	04/06/2021	Yes	No
Results article	impact of home visits on male spouses	05/02/2022	10/02/2022	Yes	No
Results article	Impact of universal home visits on child health	12/10/2021	20/09/2023	Yes	No