

Improving maternal and child health service utilization and dietary intake to enhance maternal and child health in rural areas of southern Terai, Nepal

Submission date 07/06/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 03/07/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/08/2023	Condition category Pregnancy and Childbirth	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The 2011 Nepal Demographic and Health survey showed that only 50% of women have four Antenatal Care (ANC) visits and 45% have postnatal visits. 35% of births take place in a health facility and the rest at home. Despite a decrease in maternal mortality (death rate), neonatal mortality has remained the same over the past five years. These poor health indicators show that there is a need to increase the use of Maternal and Child Health (MCH) services especially in rural areas. Although the study area is one of the districts where governmental and non-governmental organizations provide all maternal health services free of cost, the utilization of MCH services is very low. The aim of this study is to assess whether the intervention will help increase the use of MCH services, promote good nutrition, address possible barriers and improve pregnancy outcomes.

Who can participate?

Pregnant women in the second trimester (13-28 weeks).

What does the study involve?

48 wards from six village Development Committees (Dhalkewar, Digambarpur, Hariharpur, Sakhuwa, Shantipur and Tulsi) are randomly allocated to either the intervention or the control group. For the intervention group the intervention involves training, supervision and monitoring of Female Community Health Volunteers (FCHVs), and sending text messages about MCH services and diet to pregnant women or their close relatives. The control group does not receive any intervention. Participants' use of MCH services and their diet are assessed.

What are the possible benefit and risks of participating?

This intervention may help the participants to use MCH services and this may lead to better health for pregnant women, their children and their communities. There are no risks associated with this study.

Where is the study run from?
BHORE Janakpur (Nepal)

When is the study starting and how long is it expected to run for?
June 2015 to December 2016

Who is funding the study?
Janaki Health Care & Research Center (Nepal)

Who is the main contact?
Jitendra Kumar Singh (PhD Scholar)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MATRI SUMAN 2015

Study information

Scientific Title
Effect of capacity building and technological intervention on utilization of maternal and child health services in rural communities of Dhanusha district (Southern Terai) in Nepal: a cluster randomized controlled trial

Study objectives
It is hypothesized that capacity building and technological intervention will enhance the utilization of Maternal and Child Health (MCH) services by the pregnant women and will be associated with positive changes in food consumption pattern, pregnancy outcomes and child

feeding practices. Supervision, monitoring and reinforcement training will enhance the performance of Female Community Health Volunteers (FCHVs) and the use of mobile phone text messages will be feasible as a tool for health education for MCH service utilization in the intervention group as compared to the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethical Review Board of Nepal Health Research Council, 01/07/2015, reg. no. 101/2015
2. Ethical Review Committee, Institute of Medical Sciences, Banaras Hindu University, 17/10/2015, EC reg. no.: ECR/526/Inst/UP/2014 Dt. 31.1.14

Primary study design

Interventional

Study design

Prospective cluster randomized controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Pregnancy

Interventions

The intervention package to be implemented has two components to address MCH Service utilization and dietary intake.

Component 1: Capacity Building of FCHVs through Reinforcement Training and their Supervision and Monitoring.

FCHVs in the intervention arm were sensitized to the extent at they can make frequent visits to the pregnant women in their respective wards. They underwent one day extensive orientation /reinforcement training, equipping them with the knowledge and skills at the community level. The content includes the materials prepared by combining three packages:

1. Maternal and Neonatal Health (MNH) counselling package "Jeevan Suraksha" developed by USAID
 2. Nutritional package by "micronutrient initiative, Nepal" which has been adopted by the Department of Health Services, Ministry of Health and Population, Government of Nepal
 3. "Bal Paribar Mitra" monitoring format; Training of Trainers (ToT) module of Community Based - Maternal and Child Health Nutrition (CB-MCHN) project (motivation for change), UP, India.
- A system for monitoring of FCHVs is prepared. A researcher will make monthly visits to FCHVs in the intervention areas. The monitoring format for FCHVs is developed which is adopted from the "Bal Paribar Mitra" monitoring format; ToT module of CB-MCHN project (motivation for change), UP, India.

Component 2: Text messages through mobile phone to the pregnant women:

All the pregnant women in the intervention arm will receive text messages (SMS) either in Nepali or Maithili, based on the participant's language preference. The text message will be delivered manually by the researcher himself through a mobile phone. The frequency will be one message per fortnight during the 4-5-6th month and thereafter every week until delivery. During the

postnatal period up to 6 months one message will be sent per week. A package of common messages for all is prepared according to stage of pregnancy (i.e. trimester specific) and postnatal. The SMS message will be short and concise informing what they should do. Altogether 10-15 messages are created for each stages of the pregnancy and postpartum. These messages are also adopted from the training materials Jeevan Suraksha, Micronutrient Initiative-Nepal.

Added 15/05/2017:

Outcomes for antenatal care (antenatal care including weight and other measurements, and dietary diversity) was evaluated after 37 weeks of gestation (at Follow up-I). Intra-natal care (delivery by Skilled Birth Attendant, institutional delivery and child outcomes) was evaluated just after delivery (at Follow up-II). Postnatal care, child feeding practices and satisfaction of participants was evaluated just after completion of six months after delivery (Follow up-III).

Intervention Type

Behavioural

Primary outcome(s)

1. Utilization of Skilled Birth Attendant (SBA) by pregnant women at delivery. % of births for which pregnant women delivered with a skilled birth attendant (doctor, Auxiliary Nurse Midwife [ANM], or nurse) either at a health facility or at home, evaluated just after delivery (at Follow up-II)
2. Consumption of diversified diet. % of women who consumed diversified food (number of food groups consumed) by Food and Agriculture Organization (FAO) 2007 recommendations for pregnant women, evaluated after 37 weeks of gestation (at Follow up-I)

Key secondary outcome(s)

1. % of women who received four Antenatal Care (ANC) visits from a skilled provider (doctor, ANM, or other nurse), evaluated just after delivery (at Follow up-II)
2. Institutional delivery: % of births that took place at health facility (public or private), evaluated just after delivery (at Follow up-II)
3. % of mothers who received three postnatal check-ups from a skilled provider (doctor, ANM or other nurse), evaluated just after completion of six months after delivery (Follow up-III)
4. Weight gain during pregnancy: % of pregnant women with a weight gain during pregnancy (per kg/month) from the 4th month of pregnancy, evaluated just after delivery (at Follow up-II)
5. Changes in child feeding practices: % of women who initiate breast milk within ½ hour, fed colostrums, practices exclusive breastfeeding and complementary feeding in time, evaluated just after completion of six months after delivery (Follow up-III)
6. Performance of FCHV: % of FCHV reporting timely and correctly and conducted mothers meetings regularly, evaluated just after completion of six months after delivery (Follow up-III).
7. Feasibility of mobile phone text messages as tool for health education in MCH service utilization: % of women who utilized MCH Services followed by text messages, evaluated just after completion of six months after delivery (Follow up-III).

Completion date

21/12/2016

Eligibility

Key inclusion criteria

Current inclusion criteria as of 11/05/2017:

1. Pregnant women in the second trimester (13-28 weeks) of any age who visit or do not visit health facilities for MCH services in 54 clusters in given period of time
2. Dhanusha district has 101 Village Development Committees (VDCs). 64 VDCs were excluded. 39 VDCs were excluded because of Maternal and Infant Research Activities by MIRA Dhanusha and 25 VDCs were excluded because of programmatic activities (Sunaula Hazar Din) of Government of Nepal. Baseline survey was done only in 54 wards (cluster) of six VDCs selected randomly
2. The intervention in this research involved only VDCs which have SBA utilization less than 12% and 4ANC less than 40%
3. Evaluation will be done longitudinally at different points of time until 6 months after childbirth

Previous inclusion criteria:

1. Pregnant women in the second trimester (12-24 weeks) of any age who visit or do not visit health facilities for MCH services in 54 clusters in given period of time
2. Dhanusha district has 101 Village Development Committees (VDCs). 64 VDCs were excluded. 39 VDCs were excluded because of Maternal and Infant Research Activities by MIRA Dhanusha and 25 VDCs were excluded because of programmatic activities (Sunaula Hazar Din) of Government of Nepal. Baseline survey was done only in 54 wards (cluster) of six VDCs selected randomly
2. The intervention in this research involved only VDCs which have SBA utilization less than 12% and 4ANC less than 40%
3. Evaluation will be done longitudinally at different points of time until 6 months after childbirth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

413

Key exclusion criteria

1. Women in the third trimester of pregnancy
2. Women with a disability that makes the intervention difficult (for example, with hearing or sight problem or mentally handicapped)

Date of first enrolment

01/06/2015

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

Nepal

Study participating centre

Dhanusha district of Nepal

Nepal

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Sponsor information

Organisation

BHORE Janakpur

Organisation

Janaki Medical College Teaching Hospital

Funder(s)

Funder type

Charity

Funder Name

BHORE Janakpur

Results and Publications

Individual participant data (IPD) sharing plan

Due to ethical restrictions imposed by the institute ethics committee, the datasets generated during and/or analysed during the current study are/will be available upon request. Interested researchers may submit a request for the dataset to the principal investigator Jitendra K. Singh (jsingdj@gmail.com) and the dataset shall be made available after obtaining additional permission from the institute ethics committee with a reference to this trial.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/11/2018	29/01/2019	Yes	No
Results article	results	17/07/2020	10/08/2020	Yes	No
Protocol article		14/06/2018	18/08/2023	Yes	No