

The effect of community health volunteer activation on maternal and child health in Volta region, Ghana

Submission date 15/05/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Although there has been a decrease in mortality (deaths) of children under 5, there were still 44 such deaths for every 1,000 live birth around the world reported in 2013. Around 800 women worldwide die every day from pregnancy and childbirth related causes. In 2013, the under-5 children mortality rate in Ghana was 71.4 (per 1,000 live birth), which is higher than the global average. Furthermore, 2,143 women in Ghana died in pregnancy in 1990 and 2,343 were reported dead in 2013. Malaria is a significant cause of death among both children under 5 and pregnant women. Diarrhoea is also a major cause of death among children under 5 in Ghana. A number of previous studies have reported the effect of community-based health care on maternal and child health and a Community-based Health Planning and Services (CHPS) in Ghana was thoroughly designed and applied nationally to respond to the significant shortage of health workers and to improve maternal and child health. The experimental phase of CHPS introduction manifested the effect of engaging volunteer in the system, but emphasis and support on community health volunteers (CHV) in CHPS implementation has been diminished. Recently, the importance of the CHV role in CHPS is being re-emphasized and brought into the political discussion. We expect that it is a timely and significant work to provide scientific evidence to support the effect of CHVs on the promotion of health in Ghana. Here, we want to examine the effect of using CHVs in the communities on maternal and child health, through experimental research. Main outcomes of the study are improvement of contraception, maternal health and child health through prevention and treatment services focused on malaria and diarrhoea.

Who can participate?

Households with a woman aged 15-49 with at least one live birth in the past 5 years, a child under 5, and living in 40 communities of Ketu South district, Volta region in Ghana.

What does the study involve?

Communities under 9 CHPS zones are randomly selected and allocated into either the treatment or control group. In the intervention group, CHVs are given proper training, material support, incentives and regular monitoring. They are trained to promote contraception, ante-natal and post-natal care, prevention of diarrhoea in children under 5 through hand-washing and latrine

management and prevention of malaria through appropriate use of mosquito net both in children under 5 and pregnant women. CHVs also provide oral dehydration solutions (ORS) for children under 5 experiencing diarrhoea and rapid diagnostic test for malaria to those experiencing suspected fever. Accordingly, the use of CHVs are expected to promote health-related awareness and ultimately encourage healthy behaviours.

What are the possible benefits and risks of participating?

We expect that the community members, especially women in fertility and children of the intervention group will show improved health outcome. Fertile women will benefit by using proper contraception to avoid unwanted pregnancy and to meet the family planning needs. Pregnant women will have more timely treatment thanks to rapid diagnostic test provided by CHVs in the community. Children under 5 will less likely develop malaria and diarrhoea due to regular health promotion and education as well as get proper management when experiencing symptoms. The same targets in the control group will be also benefit after the first phase of the trial. We expect no risks to participating in the study.

Where is the study run from?

Communities under 9 CHPS zones in Ketu South district, Volta region in Ghana

When is the study starting and how long is it expected to run for?

February 2015 to September 2016

Who is funding the study?

Korea International Cooperation Agency (KOICA)

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The effect of community health volunteer activation on maternal and child health in Volta region, Ghana: a cluster randomized controlled trial

Study objectives

Community Health Volunteer (CHV) activation promotes maternal and child health.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ghana Health Service Ethics Review Committee, 16/07/2015, ref: GHS-ERC 07/01/15

Study design

Phase-in study cluster randomized controlled 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Maternal and child health including family planning, malaria, diarrhoea

Interventions

Activation of CHV is the main intervention of the trial and the intervention will be applied to the intervention group for a year from August 2015 to September 2016 and to the communities under control group for 5 months after completion of intervention to the treatment group. 40 communities were randomly selected from 61 communities under 9 Community-based Health Planning and Services (CHPS) compounds in the study area. They will be allocated to each treatment and control group with restricted randomization method.

We expect CHVs to be activated through provision of training, appropriate equipment for activity, incentives and regular monitoring. Main tasks of CHVs will be home visits to assigned households, support to community health nurse (CHN) activity in the community and outreach program, participation in the monthly review meeting at CHPS with CHNs and other CHVs, regular reporting and surveillance. Home-based counselling and care through home visit is a key activity of CHVs. They will deliver key messages to promote health-related perception and behavior, and deliver preventive and curative services to improve specific health outcomes. Key messages that will be delivered by CHVs include promotion of injectable and implant for contraception, delivery by a skilled birth attendant, utilization of mosquito net, proper hand-washing at 4 critical points, management of latrine and constant check on child's growth. Preventive and curatives measures that CHVs are allowed to take are provision of ORS to the under-5 children experiencing diarrhoea and examination of fever with thermometer and malaria with rapid diagnostic test. Initial training for CHVs will be consist of 5 day program with theoretical and field training. Further refresher training is planned to strengthen the capacity of CHVs. In order to support activities of CHVs, necessary tools and material incentives will be provided. Equipment list includes rain coat, ID card, logbook, notepad, digital thermometer, educational materials and others. Incentives are composed of phone credit to facilitate theirs communication with the mothers and CHNs and some food items. CHVs are encouraged to participate in the monthly review meeting held by CHNs at CHPS to report and share the progress and challenges.

Process evaluation will be carried out throughout the study period to monitor and assess implementation of the interventions by household survey, key documentation review and observation. Four times of household survey is planned and review of key documentations such as CHV logbook, community registry, CHPS inventory log and meeting minutes will be conducted mainly at monthly review meeting. Direct observation will be accompanied with household survey and document review process.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measures as of 03/05/2019:

1. 14-day diarrhoea prevalence among under-five children, assessed on the basis of caregiver's reports at baseline, and 6- and 12-month follow-up
2. 14-day fever prevalence among under-five children, assessed on the basis of caregiver's reports at baseline, and 6- and 12-month follow-up

Previous primary outcome measures:

1. Use of contraceptive methods (implant or injectable) in the last 6 months (%)
2. Percentage of pregnant women taking ante-natal care of pregnant women (1 time & 4 or more times)
3. Percentage of women taking post-natal care (within 48 hours & within 6 weeks after delivery)
4. Percentage of pregnant women with fever taking rapid diagnostic test for malaria
5. Percentage of under-5 children with fever taking rapid diagnostic test for malaria
6. Percentage of under-5 children with diarrhoea taking oral dehydration solutions (ORS)
7. Incidence of malaria in under-5 children in the last 2 weeks
8. Incidence of diarrhoea in under-5 children in the last 2 weeks

Measurement methods:

Indicators to measure achievement of the primary outcomes will be assessed through 3 times of household survey; April 2015, February 2016, August 2016. Baseline survey was conducted in April 2015 and midterm survey in February 2016. An endline survey in August 2016 will be carried out after the initiation of intervention in July 2015.

Secondary outcome measures

Current secondary outcome measures as of 03/05/2019:

1. Family planning practices of caregivers using any of these methods. The following family planning practices were assessed on the basis of self-reports at baseline, and 6- and 12-month follow-up: female/male sterilization, intrauterine devices, injectable contraceptives, implants, pills, female/male condoms, the standard-days method, the rhythm method, the lactational amenorrhea method, and withdrawal
2. Case management for child diarrhea. The practice of oral rehydration salt administration among children under-five with diarrhea was assessed on the basis of caregiver's reports at baseline, and 6- and 12-month follow-up
3. Case management for child fever. The practice of taking a rapid diagnostic test for malaria among children under-five with fever was assessed on the basis of caregiver's reports at baseline, and 6- and 12-month follow-up

Previous secondary outcome measures:

1. Perceptual and behavioral change in hand-washing at 4 critical points
2. Perceptual and behavioral change in management of latrine
3. Perceptual and behavioral change in utilization of mosquito net
4. Perceptual change in use of contraception methods
5. Perceptual change in diarrhoea treatment using ORS
6. Perceptual change in malaria diagnosis using RDT
7. Perceptual change in taking ANC/PNC
8. Perceptual change in delivering by SBA

Measurement methods:

Indicators to measure achievement of the secondary outcomes including those key ones will be assessed through 4 times of household survey accompanying some direct observations;

November 2015, February 2016, May 2016, August 2016. Survey in February and August 2016 will be embedded in the midterm and endline survey to measure primary outcomes. Baseline survey conducted in April 2015 will provide the baseline data to measure the change.

Overall study start date

01/02/2015

Completion date

30/09/2016

Eligibility

Key inclusion criteria

Women aged 15-49 with at least 1 live birth in the past 5 years and children under 5 years

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

2000 households (2000 mothers and 2000 under-5 children)

Total final enrolment

3891

Key exclusion criteria

1. Households without a woman aged 15-49 with at least 1 live birth in the past 5 years
2. Households rejecting participation of the study

Date of first enrolment

18/04/2015

Date of final enrolment

04/05/2015

Locations

Countries of recruitment

Ghana

Korea, South

Study participating centre

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Study participating centre

Volta Regional Health Directorate, Ghana Health Service

Volta regional health directorate

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Volta region

Ghana

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Sponsor information

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Funder(s)

Funder type

Government

Funder Name

Korea International Cooperation Agency

Alternative Name(s)

KOICA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date**Individual participant data (IPD) sharing plan**

Data cannot be shared publicly because of Ghana government policy. Data are available from the Ghana Health Service (via Dr Anthony Ofosu, anthony.ofosu@ghsmail.org) for researchers who meet the criteria for access to confidential data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/01/2017		Yes	No
Results article	results	14/06/2019	17/06/2019	Yes	No
Other publications	Economic evaluation	11/05/2023	10/07/2023	Yes	No