ISRCTN90618993 https://doi.org/10.1186/ISRCTN90618993

Study protocol for Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE) program

Submission date
25/08/2014

Recruitment status
No longer recruiting

Registration date
03/09/2014

Overall study status
Completed

Last Edited
28/06/2021

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Global health agencies have advocated continuum of care (CoC) in order to improve maternal, newborn and child health (MNCH) care. Although CoC-related interventions have improved care, it is unclear whether they were effective in current practices in more 'real-world' scenarios. Moreover, it is unclear whether health outcomes will be improved by filling the gaps of CoC. As a result, the Japanese government launched the MNCH model project in 2012, Ghana Ensure Mothers and Babies Regular Access to Care (EMBRACE) implementation research project, to improve care. Ghana is one of the countries which have faced a significant challenge to improve MNCH status. In particular, MNCH status was poor in remote areas and care-seeking decisions were delayed for ill mothers and babies. Additionally, not all of MNCH services are used by mothers and infants continuously. Especially, the neonatal care is less paid attention. However, when health services during pregnancy, at the time of birth and after the birth of the baby were appropriately used, the risk of death of newborn babies could be reduced. Moreover, Ghana has multiple localities which are formed by particular characteristics of each area. The diversity of local characteristics implies the need for flexibility in health service provision. It explains why the implementation studies should be conducted in Ghana in different real contexts. Thus, this study aims to evaluate the impact of increased CoC completion on MNCH status in Ghana. Specific objectives are proposed for intervention and implementation phases. We want to see the effect of the EMBRACE interventions on the CoC completion, and to evaluate the impact of the interventions on MNCH status.

Who can participate?
Women of reproductive age between the ages of 15 and 49 years who live in the areas of Dodowa, Kintampo and Navrongo in Ghana.

What does the study involve?
Areas will be randomly allocated to the intervention or the control group. We will conduct a CoC intervention package to the target population in the intervention group. The MNCH service

providers will receive a training session regarding CoC and the procedures to be performed. For the control group, we will introduce the intervention to them immediately when a positive impact is seen.

What are the possible benefits and risks of participating?
This intervention package is not invasive and will be conducted following the national guidelines. Thus, the participants will not be exposed to specific risks. By participating in this study, they benefit by improved knowledge and care of mothers and newborn babies. Health facilities of the intervention group will receive a set of services after birth, motorbikes, or rest beds, if there are no available ones.

Where is the study run from?
The study is run from Dodowa, Kintampo and Navrongo in Ghana.

When is the study starting and how long is it expected to run for?
The study starts in October 2014 and is expected to run until March 2016.

Who is funding the study?
Japan International Cooperation Agency (JICA), Japan.

Who is the main contact?
Prof. Masamine Jimba
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Study protocol for Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE) program: an effectiveness-implementation hybrid research trial

Study objectives
Maternal and child health can be improved if continuum of care (CoC) is properly completed in maternal, newborn, and child health (MNCH). The CoC completion will be attained by filling the gaps of health service coverage, and linking the health service delivery from pre-pregnancy to postnatal care, at home, community, and health facilities. Thus, the hypothesis of this study is that the MNCH will be improved by filling the gaps of CoC coverage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of the Graduate School of Medicine, the University of Tokyo; 19/06/2014; ref: 10513
2. Research Ethics Committee of Ghana Health Service: 31/07/2014; ref: GHS-ERC: 13/03/14
3. Institutional Review Board in Dodowa Health Research Center: 14/07/2014; ref: GHS-DHRC: 280214
4. Institutional Review Board in Kintampo Health Research Center: 04/06/2014; ref: 2014-11
5. Institutional Review Board in Navrongo Health Research Center: 28/05/2014; ref: NHRCIRB137

Study design
Effectiveness-implementation hybrid design by multicenter approach cluster randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
CoC in MNCH/pregnant woman, mother, newborn baby/maternal and neonatal morbidity, neonatal mortality

Interventions
In each area of the HDSS site, we will assign sub-district based clusters randomly (Dodowa: 8, Kintampo: 12, Navrongo: 12 clusters) to either the intervention or the control arm.

1. Interventions commonly implemented in Dodowa, Kintampo, and Navrongo HDSS sites
1.1. Utilization of CoC card
1.2. CoC orientation for health service providers
1.3. Home visit postnatal care (PNC)

2. Interventions implemented in Dodowa and Navrongo HDSS sites only: 24-hours retention of mothers and newborn babies after delivery at health facility

Control arm receives the intevention as soon as a positive impact is seen in the intervention group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
CoC completion rate among mothers and newborn babies. The CoC completion is defined as taking following all health services: antenatal care four times, delivery assisted by skilled birth attendants, PNC three times (within 48 hours, at 7 days, at 6 weeks after delivery).

Secondary outcome measures
Intervention outcomes:
1. PNC rate within 48 hours after delivery
2. Complication rate which requires mothers or newborn babies hospitalization of more than 24 hours
3. Perinatal mortality rate (PMR), neonatal mortality rate (NMR)

Implementation outcomes:
1. Intervention coverage of target population
2. Adoption in CoC card utilization or PNC within 48 hours by mothers retention at health facility or by home visit
3. Fidelity in CoC card utilization or PNC within 48 hours by mothers retention at health facility or by home visit
4. Implementation cost
5. Sustainability

Overall study start date
01/10/2014

Completion date
31/03/2016

Eligibility

Key inclusion criteria

Women at reproductive age between 15 and 49 years old and match to the following criteria:
1. Participants of the baseline survey: Those who gave birth between 1st September 2012 and 30th June 2014
2. Participants of the follow-up survey: Those who passed all the period from their 1st ANC to six weeks postpartum during the intervention period (1st October 2014 and 30th September 2015)
3. Participants of the intervention: Those who are in the period between pregnancy and six weeks postpartum during the intervention period (1st October 2014 and 30th September 2015)
4. Targets of the Health and Demographic Surveillance System (HDSS) data:
4.1. Those who have given birth between 1st September 2012 and 30th June 2014 for baseline HDSS data
4.2. Those who are in the period between pregnancy and six weeks postpartum during the intervention period (1st October 2014 and 30th September 2015) for follow-up HDSS data

Participant type(s)
Other

Age group
Adult

Sex
Female

Target number of participants
1. Participants of the baseline survey and follow-up survey: 1,500 women for each survey (intervention: 750, control: 750) 2. Participants of the intervention: 8,500 women for the intervention

Total final enrolment
1490

Key exclusion criteria
Women:
1. Who refused participating with the intervention
2. Who decline to be interviewed
3. Who have migrated out of the HDSS sites

Date of first enrolment
01/10/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
Ghana

Japan

Study participating centre
The University of Tokyo
Tokyo
Japan
113-0033

Sponsor information

Organisation
Japan International Cooperation Agency (JICA) (Japan)

Sponsor details
1-6th floor, Nibancho Center Building 5-25
Niban-cho, Chiyoda-ku
Tokyo
Japan
102-8012

Sponsor type
Government

Website
http://www.jica.go.jp/english/index.html

ROR
https://ror.org/022es3t03

Funder(s)

Funder type
Government

Funder Name
Japan International Cooperation Agency (JICA) (Japan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/01/2015		Yes	No
Results article	results	11/09/2019	17/12/2020	Yes	No
Other publications	evaluation	27/03/2021	09/04/2021	Yes	No
Other publications	evaluation	25/06/2021	28/06/2021	Yes	No