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Effect of telephone-based postnatal care on the health of mothers and their newborns

Submission date
22/03/2021

Recruitment status
No longer recruiting

Registration date
09/04/2021

Overall study status
Completed

Last Edited
31/10/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The postnatal period (period starting from delivery of the baby up to six weeks after delivery) is a very critical period for newly delivered mothers and their babies. This is because it provides an opportunity for identifying and correcting complications that easily result in the illness or death of both mother and baby. However, it is one of the areas of mother and child health programs that receive little attention. Counselling for mothers before they are discharged from health facilities is usually done in groups and mothers are unable to get their individual concerns addressed. Some mothers are also discharged from the health facilities too early and given counselling at a time when they are either too exhausted or distracted to pay attention. As a result, very little information from the counselling is retained. Some mothers also face challenges at home regarding care for their babies and their own health. Some also lack the necessary support to resist pressure from families and friends who impose harmful traditional postnatal care practices. These challenges require providing mothers with easy access to a health worker to help improve mother and baby's health and adopt healthy postnatal practices. In order to achieve this, the researchers are taking advantage of the wide availability of mobile telephone to counsel and maintain contact with mothers throughout the postnatal period and measure how it changes health outcomes in the mothers and their babies. The researchers want to test a new method of postnatal care. This method includes in addition to the usual postnatal care, making telephone calls to mothers to reinforce the postnatal counselling message a few hours after they reach their various homes after discharge from the hospital, as well as providing them with a dedicated telephone number of a health worker whom they can reach out to anytime to address their concerns in the first six weeks after delivery. They want to test how this new method will be different from the usual postnatal care received by mothers and their newborn babies at the health facilities.

Who can participate?
Newly delivered mothers aged 18 years and above and their newborn babies delivered at the two participating hospitals who have been discharged from the hospital but has not left the hospital, are not too ill to participate in this study and are likely to stay in the Greater Accra Region for at least three months after delivery. The mothers and their babies should not be participating in any other intervention and the mothers should be willing to participate in the study.

What does the study involve?
The study involves comparing telephone-based postnatal follow-up in addition to usual postnatal care with the usual postnatal care given by hospitals. Participants are randomly allocated to either of two groups (with each participant having an equal chance of being in either group). Participants and researchers do not have a choice in the group to which they are assigned. Participants in the first group will receive in addition to the usual postnatal care, telephone-based postnatal follow up by receiving phone call from a health worker within two days after discharge from the hospital. They will also be given telephone contact of a health worker who they would call for support in clarifying and given guidance on any concerns they might have for a period of six weeks after delivery. The participants in the second group will receive the usual postnatal care given by the hospital. Mother-baby pairs are assessed by the research team and have passed the initial assessment. They are then randomly assigned to either of the two groups of the study. Mothers are asked to answer questions about themselves, their family, pregnancy and delivery. Mother-baby pairs in the first group of the study are then called within 48 hours after leaving the hospital and counselled on their own care and care of their newborns using a standard guideline. They are given the opportunity to ask questions for clarification. They are then given the telephone number of the health worker, who is available to support them with the appropriate care should they have any concerns relating to their own health or that of their babies for the first six weeks after delivery. After three months of follow-up, the mothers in both groups are interviewed on their health, their babies' health and breastfeeding, postanal clinic attendance and family planning practices. The study is expected to last for seven months.

What are the possible benefits and risks of participating?
Participants may benefit directly from this study as a result of the children and their mothers being followed up by health workers and referred to appropriate health facilities when ill. Also, the findings from the study are expected to benefit mothers and their babies because they are likely to improve maternal and infant health outcomes. The Family Health Division of the Ghana Health Service may also use the results in planning postnatal care programs for mothers and their babies. The research by itself will not pose any major risks to the participants. However, there is a potential minor risk of some questions creating discomfort to participants. The research assistants are well trained to ask the questions in a humane manner so as to minimize this risk. Participants also have the right not to answer any question or discontinue the interview without attracting any penalty.

Where is the study run from?
Two major hospitals in the Greater Accra Region of Ghana are taking part in this study. These are Tema General Hospital in the Tema Metropolis and Greater Accra Regional Hospital in Accra Metropolis

When is the study starting and how long is it expected to run for?
January 2020 to April 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Donne Kofi Ameme (Principal Investigator)
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
GHS-ERC003/06/20

Study information

Scientific Title
Effect of telephone-based postnatal follow-up on infant and maternal health outcomes in Accra and Tema metropolises: a randomised controlled trial

Study objectives
Mother-baby pairs followed up by a combination of telephone-based postnatal health education and routine health facility based postnatal care have better maternal and infant health outcomes than those followed up with routine health facility-based postnatal care alone

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 21/08/2020, Ghana Health Service Ethics Review Committee (Research & Development Division, Ghana Health Service, P.O.Box MB190, Accra, Ghana; +233-0302-960628; ethics.research@ghsmail.org), ref: GHS-ERC003/06/20

Study design
Interventional open label randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Improving the general health of nursing mothers and their newborns

Interventions
Mother-baby pairs are randomised into either of two arms of postnatal follow-up interventions:
1. Telephone-based follow up in addition to routine health facility based follow up; and
2. Routine health facility based follow up alone.
Intervention will be a telephone-based follow up in two parts:

Part 1: Mothers are called within 48 hours after discharge and provided with counselling on care of the baby including infant feeding, how to keep baby warm and addressing family challenges.
Part 2. Mother is given telephone access to a midwife on-call during the first six weeks after delivery (postnatal period) to ask questions about their own or babies' health and care, when the need arise.

The mother-baby pairs in both arms were followed up after discharge till three months after delivery. Mother-singleton baby pairs in the intervention arm were followed up via telephone call in addition to hospital's routine follow up while those in the control arm had only the routine health facility based postnatal care. Data was collected on maternal, fetal and newborn characteristics at baseline, and on infant and maternal health outcomes within three months of follow up.

Intervention Type
Behavioural

Primary outcome(s)
Mothers' self report of:
1. Infant illness episode (acute illness episode for which help was sought) episodes within first three months of life measured three months after delivery
2. Maternal illness (acute illness for which help was sought) within first three months of postnatal period measured three months after delivery

Key secondary outcome(s))
Mothers' self report of:
1. Exclusive breastfeeding at three months of age
2. Maternal family planning use within the first three months of postnatal period measured at three months after delivery

3. Maternal post-partum depression at three months after delivery
4. Postnatal clinic attendance at 7-14 days and 6 weeks

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Mother should be at least 18 years of age and have access to a functional mobile phone
2. Mother and baby should be discharged from hospital but not have left the hospital
3. Babies and their parents should not be participating in another intervention
4. Mother-baby pairs who do not intend to move out of the Greater Accra Region within three months after delivery
5. Mother should be willing to consent to participate in the study

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Babies born with severe congenital anomaly that require major medical and or surgical intervention
2. Babies born preterm
3. Babies admitted to NICU for severe illness after delivery
4. Either or both parents being a health worker

Date of first enrolment
15/09/2020

Date of final enrolment
30/12/2020

Locations

Countries of recruitment

Ghana

Study participating centre
Greater Accra Regional Hospital
P.O.Box 473
Accra
Ghana
GH

Study participating centre
Tema General Hospital
P.O.Box 14
Tema
Ghana
GH

Sponsor information

Organisation
University of Ghana

ROR
https://ror.org/01r22mr83

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/10/2022	31/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes