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A trial exploring the feasibility of using telephone support (SMS and call) as a means of supporting young mothers (12-19 years) in Western Kenya soon after giving birth

Submission date
21/06/2017

Recruitment status
No longer recruiting

Registration date
17/07/2017

Overall study status
Completed

Last Edited
26/11/2021

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
New mothers require a lot of support to ensure a health mother and healthy babies. This can range from giving advice about breastfeeding, health problems, postnatal (after giving birth) depression and infant health. Young mother's are particularly vulnerable after giving birth. In Kenya, woman receive the normal postnatal care which includes clinical appointments, health education and a booklet about maternal and infant care. A new programme has been developed by a group of midwives in Kenya, who are highly experienced in providing care to young mothers and their babies/infants. It comprises motivational health messages using telephones or text messages for the young mothers, specially helping them in caring for themselves and their babies/infants soon after birth (up to 10 weeks after birth). The young mothers who have had a normal birth are encouraged to participate in a programme like this to provide them with extra support. The aim of this study is to assess the feasibility and acceptability of telephone support intervention (in form of short text messages and a telephone call) at scheduled periods among young mothers aged 12-19 in Western Kenya.

Who can participate?
New mothers aged 12 to 19 and qualified midwives at the study hospitals.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard care after giving birth. Those in the second group receive the usual care and additional support through weekly text messages and telephone calls every three weeks for ten weeks in total. At the end of the study, participants are asked if they would like to participate in voluntarily focus group discussions or interviews. Participants are assessed to see if the telephone support improved their and their baby's health.

What are the possible benefits and risks of participating?
There are notable benefits however participating midwives may improve their practice by reflecting on their routine care. There are no notable risks with participating.

Where is the study run from?
1. Moi Teaching & Referral Hospital (Kenya)
2. Kakamega County Referral Hospital (Kenya)

When is the study starting and how long is it expected to run for?
September 2015 to December 2018

Who is funding the study?
Lugina Africa Midwives Research Network (LAMRN) and the University of Manchester (UK)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Clinical trials ID...

Study information

Scientific Title
A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Study objectives
The aim of this study seeks to explore the feasibility and acceptability of telephone support intervention as a means of supporting young mothers during the immediate postnatal period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Manchester Research Ethics Committee, 28/09/2016, ref: 16427
2. Moi Teaching & Referral Hospital/Moi University, 02/02/2017, ref: FAN: IREC 1811
3. Kakamega County General Hospital, 01/11/2016, ref: cgh/kak/gen/30/63

Study design
Pilot randomised controlled trial mixed method

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not accessible in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Midwifery care - postnatal care of young mothers

Interventions
This pilot study seeks to assess the feasibility and acceptability of telephone support intervention in the postnatal care of young mothers. The sample size follows accepted guidelines for feasibility/pilot studies with a consideration of an attrition rate of 25%. Sample allocation to a group is performed using the SNOSE (sequentially numbered, opaque sealed envelopes) approach, with a set of random allocation numbers generated by a computer software program. The set of random numbers is performed by someone (biostatistician) who is independent of the intervention and data collection.

The mixed methods approach is applied as it is suitable in assessing feasibility studies as it may provide varied data that may be useful in informing future (definitive) trial. Eligible participants are duly informed of all the study procedures and their informed consent sought before being recruited. The intervention is developed using a Delphi technique, which is conducted involving midwives. The information sought is based on their professional expertise as midwives, and thus no personal data is collected. Moreover, since the information sought is practice-related, written consent is not be sought. However, a verbal consent is sought and the midwives are asked to voluntarily participate in the Delphi.

The trial seeks to test telephone support intervention (short message service-SMS; and a call) among young mothers (12-19 years) in western Kenya. The study participants are recruited and randomised to either the intervention or control groups during the first week postpartum (before discharge from maternity unit) at the respective study centres and followed up until the tenth week postpartum.

The usual care group receives the routine care which consists of postnatal health education, scheduled clinical appointments and a Mother & Baby booklet for reference on maternal and infant care.

At the intervention phase, the intervention group receives the usual care and a telephone-support intervention in the form of motivational health messages (SMS) on weekly basis and a follow up telephone call after every three weeks, and compared to the usual care (control) group.

The tenth week corresponds to the second booking for clinic appointment after birth at the Maternal and Child Health welfare clinic, which almost all mothers and their infants attend, and thus provide an ideal opportunity to evaluate the intervention. Maternal and infant outcomes are assessed at the tenth week postpartum in both groups for comparison. Midwives working in the postnatal units of the two hospitals are also be interviewed about their perceptions of the telephone support intervention as a supportive care strategy for young mothers, including the unit heads.

Midwives working in the postnatal units of the two hospitals will also be interviewed about their perceptions of the telephone support intervention as a supportive care strategy for young mothers, including the unit heads at 12 weeks postpartum.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility and acceptability of the intervention is measured using reviews of the quality data available that supports a main trial and qualitative interviews at ten weeks for young mothers and 12 weeks for midwives
2. Quality of data available that support a main trial by reviewing patient notes/files at baseline

Secondary outcome measures
1. Maternal social support is measured using the maternal social support at ten weeks postpartum
2. Maternal self-esteem is measured using the Rosenberg Self-esteem scale at ten weeks postpartum
3. Mother infant bonding is measured using the postpartum bonding instrument at ten weeks postpartum
4. Postnatal depression is measured using the Edinburgh Postnatal depression scale at ten weeks postpartum

Overall study start date
21/09/2015

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. All young postnatal mothers aged 12-19 years who have given birth to a singleton healthy baby at term at the respective centres (MTRH and KCRH)

2. Those for whom consent has been sought and/or those whose parents/guardians consent, and willing to participate in the study
3. Postnatal young mothers who own a mobile phone and are able to use common mobile telephone operation services
4. Ability to read telephone text to a basic level of understanding
5. Qualified midwives and/or nurse-midwives with more than one year experience working in maternity setting

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Female

Target number of participants
The study aims at recruiting at least 50 participants (sample size, n=25 per group based on accepted guidelines for pilot/feasibility studies) for the quantitative data; and between 15-20 participants for qualitative data. Midwives will also be purposively selected in the two centres and interviewed until data saturation is attained. The Delphi will involve 20-30 midwives.

Key exclusion criteria
1. Young postnatal mothers who have given birth through caesarean, or who had multiple pregnancies and/or whose babies developed birth complications or have congenital anomalies
2. Mothers who have no capacity to consent and/or participate (with severe mental disability /illness and/or learning disability. These groups of mothers will be excluded since they may require specific care due to their complex needs.

Date of first enrolment
11/05/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Kenya

Study participating centre
Moi Teaching & Referral Hospital
P.O. Box 3 - 30100
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Study participating centre
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Sponsor type
University/education

Funder(s)

Funder type
Research council

Funder Name
Lugina Africa Midwives Research Network (LAMRN)

Results and Publications

Publication and dissemination plan
The findings of this study will be shared through journal publications and relevant conferences, with strict observation of ethical principles.

Intention to publish date
30/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Elijah Kirop at elroprotich@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Thesis results		01/01/2019	26/11/2021	No	No