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Advancing care and support for women and families after stillbirth or neonatal death in Uganda and Kenya

Submission date 04/02/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 25/02/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/08/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Globally, 2.6 million babies a year die shortly before, during or soon after birth. More than half of these deaths occur in Sub-Saharan Africa, where the average rate is about eight times higher than in wealthy nations. It is well established that stillbirth is a distressing and traumatic experience for parents with long-lasting effects such as depression and other serious mental health issues, which are linked with higher rates of physical health problems, relationship and family breakdown. Reducing the impact of stillbirth has been identified as an important international health priority for sustainable development. Preventing as many stillbirths as possible through improvements in maternity and general healthcare is very important, but it is also imperative that good care is provided for women and families whose baby dies. Research across many different countries has shown that parents are not always treated with respect and compassion or offered the support they need after stillbirth. This is important; all people wherever they live should have a right to expect basic humane care after the death of a baby. Poor experiences with healthcare can impair adjustment and recovery, impair the parent's ability to care for others (including remaining children), and also might deter them from accessing health services when the need arises in the future. A study in eastern Uganda showed that the health system and community support structures were inadequate in providing support to affected families. Recent research in Kenya and Uganda also identified lack of support for parents in facilities and after discharge home in Kenya and Uganda. Common practices surrounding stillbirth in some countries caused distress to parents, including not being encouraged to see and hold stillborn babies and lack of public mourning. Lack of education and support from health systems made it more difficult for professionals to provide good support. This study will examine the acceptability and feasibility testing of a new package of care to improve support for parents after stillbirth or neonatal death in Kenya and Uganda and the feasibility of a full-scale trial to evaluate the effectiveness of the package.

Who can participate?

1. Women aged 18 or over, in the immediate postnatal period, whose baby was stillborn or died soon after birth
2. Their partners and family members, aged 18 or over

3. Health workers (midwives, nurses, doctors and support staff) and peer supporters directly involved in the delivery of the study intervention or who provide care or services to women after stillbirth in facilities

What does the study involve?
Health workers and support staff with an interest in bereavement care in two facilities will come together forming a Perinatal Bereavement Care group that will act collectively to develop strategies to improve care for women and families. Members will act as Bereavement Champions to drive improvement in individual clinical areas. A network of community peer supporters linked to the group will be developed to offer telephone support to women in the early postnatal period. This change will be introduced with a small group of women in two hospitals in Kenya and Uganda and compared with similar women who received care immediately prior to the change. The researchers will assess whether parents are willing to take part and stay in the research study, whether the change works as planned, and the best ways of assessing the effect on well-being and maternity services.

What are the possible benefits and risks of participating?
This research will allow the researchers to understand how this new package to improve bereavement care works in practice, whether changes are needed and if it is possible to do a larger research study to prove that it helps women and families and is cost effective. It is hoped that women in phase 2 of the study will find the extra support useful, but it cannot be guaranteed that it will be. The main risk is potential for emotional distress. The period immediately following the death of a baby is very traumatic for parents, families and health workers and there is potential for emotional distress during participation in research during this time. For this study, women and families might exhibit emotional distress during recruitment, contacts with peer supporters, during the completion of questionnaires or interviews with the research assistant. This could occur when discussing experiences related to the recent death of the baby and their emotions and feelings.

Where is the study run from?
1. College of Health Sciences, Makerere University (Uganda)
2. School of Nursing Sciences, University of Nairobi (Kenya)

When is the study starting and how long is it expected to run for?
August 2019 to July 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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2. Prof. Tina Lavender
Tina.lavender@lstmed.ac.uk
(updated 02/09/2021, previously: tina.lavender@manchester.ac.uk)

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-7322-11551

Study information

Scientific Title
Advancing care and support for women and families after stillbirth or neonatal death in Uganda and Kenya: a feasibility study

Study objectives
To assess the feasibility of a full-scale evaluation to assess the effectiveness of a co-produced multicomponent intervention to improve immediate care in facilities and postnatal support after stillbirth or early neonatal death for women and families in Kenya and Uganda.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/08/2019, University of Manchester, Manchester UK, UREC committee 4 (University of Manchester Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; Tel: +44 (0)161 275 2206 /2674; Email: research.ethics@manchester.ac.uk), ref: 2019-7322-11551
2. Approved 29/10/2019, Makerere University College of Health Sciences REC (School of Health Sciences Research and Ethics Committee
Makerere University, PO Box 7072, Kampala, Uganda; Tel: +256 (0)200903786; Email: healthsciences.irb@gmail.com), ref: 2019-059
3. Approved 27/11/19, University of Nairobi/Kenyatta National Hospital Ethics and Research Committee (PO Box 19676 Code 00202, Nairobi, Kenya; Tel: +254 (0)202766300; Email: uonknh_erc@uonbi.ac.ke), ref: P828/09/2019

Study design
Pre and post mixed methods feasibility study conducted in two sites over 12 months using a cohort design

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact detail to request a participant information sheet

Health condition(s) or problem(s) studied
Care after stillbirth or neonatal death

Interventions
A mixed-methods ‘before and after’ study, conducted over 12 months, will assess whether a full-scale trial to test the effectiveness of an intervention to improve care and support after stillbirth or neonatal death in sub-Saharan Africa is feasible.

Intervention: Developed during previous and going co-production activities with the NIHR Stillbirth Research Group UK and Africa research teams, stakeholder and community engagement groups in Kenya and Uganda, will include two key components:

1. A Perinatal Bereavement Care Group to be set up in each facility and will meet 4-6 weekly during the intervention period to develop a vision for good bereavement care, strategies and activities to improve care in the facility including the development of evidence-based care pathways. The group will include:
1.1. Bereavement care champions, identified from existing health workers, 2 from each area (labour, postnatal ward, antenatal clinic, neonatal unit), who currently provide care to families after stillbirth or neonatal death.
1.2. Service managers, community engagement representatives and research team facilitators Group members will be offered training to extend knowledge of parent's needs after stillbirth and behaviour change techniques to support better practice.
2. A community peer support network, supported by Perinatal Bereavement Care Group
2.1. Four to six volunteer peer supporters per facility will be identified from existing networks; criteria will include women with previous experience of stillbirth or neonatal death, at least 12 months ago, does not have severe mental health issues. Will receive training from the research team.
2.2. Will offer telephone peer support to postnatal women during the intervention period, initiated from 2 weeks after hospital discharge
2.3. Peer supporters will link with Bereavement Care Champions/Group in facilities for support, debriefing, advice and referrals

Study Setting: Two maternity units; Kenyatta National Hospital, Nairobi, Kenya and Naguru Hospital, Kampala, Uganda.

The study will be conducted in two phases:
Phase 1 ('Before' intervention: approx. August 2019-January 2020) women and families will receive current postnatal care offered by the facility.
1. Training packages will be developed for the Perinatal Bereavement Care Group and Bereavement Champions.
2. To assess the feasibility of data collection, the researchers will approach as many postnatal women as possible experiencing a stillbirth or neonatal death in the included facilities from September to November 2019, aiming to recruit 20 to 30 women per country (maximum 60 total sample for this phase)
3. Participants will be asked to provide demographic, medical and birth data at recruitment and at 8 weeks after the birth, health and health care utilisation data will be obtained and a short psychological questionnaire completed.
4. Follow up for phase 1 participants will be completed by January 2020.
5. Perinatal care group members, bereavement champions and peer supporters will be identified and trained during December 2019 and January 2020 to minimise contamination between the study phases
6. To allow overall comparison with participants recruited to the study, the researchers will seek permission to extract anonymised data for all stillbirths and neonatal deaths occurring from August 2019-July 2020 from the facility birth registers.

Phase 2 ('After' intervention phase: approx. February 2020-July 2020); women and families will continue to receive current postnatal care and the intervention will be introduced in both facilities.
To assess the feasibility of data collection, acceptability of the intervention and recruitment and retention of participants the researchers will:
1. Approach as many postnatal women experiencing a stillbirth or neonatal death in the included facilities as possible from March to May 2020, aiming to recruit a further 20-30 women, (maximum sample 60 for this phase).
2. Participants will be offered the peer support component at study recruitment (not sooner

than 2 weeks after discharge from facilities).
3. Demographic, medical and birth data will be collected at recruitment; Participants will then be followed up 8 weeks after birth to complete health and psychological questionnaires and be invited to take part in a one to one interview exploring experiences of postnatal support.
4. Data for recruitment and numbers of participants who stay in the study until completion will be collected
5. Invite partners and family members of women recruited in phase 2 (up to 10 per country; total sample of 20) to an interview to explore their experiences around 8 weeks after the birth.
6. Provide the Perinatal Bereavement Care Group, bereavement champions and peer supporters with intervention logs to record delivery of the intervention and invite them to an interview (up to 20 per country) at the end of the study.
7. Assess wider impacts on services and care in facilities by inviting all health workers providing care for women experiencing a stillbirth or neonatal death, but not directly involved in delivering the intervention, to complete a short questionnaire at the end of the study.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment and retention of women in the study:
1.1. Women who fulfill the eligibility criteria, women who are invited to participate in the study, those recruited and any participants who leave the study before completion, recorded in a participant log
1.2. Reasons for non-recruitment (e.g. refusal to participate, language barrier) will also be recorded. Permission will be sought to collect data on reasons for non-participation from women, partners/family members and health workers who have provided contact details but decline to take part
1.3. Reasons for withdrawal and loss to follow-up documented during the course of the study

Secondary outcome measures
1. Demographic and clinical data: investigator-designed case report forms will be used to collect data for women participants via patient health records (including hospital, patient-held and electronic records) and self-report (where no secondary source available): demographic (age, ethnicity, socioeconomic status [highest level of education, occupation]) and obstetric history, index pregnancy data including the onset of labour, mode of birth, maternal and infant outcomes, cause of death (if known) length of hospital stay, and postnatal complications/all healthcare utilisation and access to external support up to 8 weeks postnatal. Data will be collected at recruitment and 6-8 weeks post-birth (study completion). Basic demographic data (age, ethnicity, socioeconomic status, etc) will also be collected via self-report for participating partners/family members, health workers and support staff at recruitment. Anonymised routinely collected clinical data for all births resulting in stillbirth or early neonatal death, in the included facilities during the study period will be extracted from the hospital birth registers. This will include maternal age, county of residence, occupation classification, medical and obstetric history (previous pregnancies, mode of birth, outcomes), index pregnancy data including the gestation, onset of labour, mode of birth, maternal and infant outcomes, cause of death (if known) and length of hospital stay. This will permit assessment of the feasibility of comparison and assessment of the potential for selection bias in sample taking part in the research.
2. Acceptability of study processes and the intervention (phase 2) captured by semi-structured face to face (or telephone) interviews with:
2.1. Women participating in the study during phase 2 (N up to 60; up to 30 per country) 6 -8 weeks after the birth

2.2. Partners and family members of women participating in phase 2 (N; up to 30; up to 15 per country) 6-8 weeks after the birth
2.3. Health workers and others (e.g. parent peer supporters) involved in the delivery of the intervention (up to 30; up to 15 per country) at the end of phase 2.
3. Uptake and additional impacts of the intervention on the practice and environment of care captured by:
3.1. An intervention log completed by bereavement champions and peer supporters will summarise all study-related activities to determine what was done, when and by whom. This will include training, meetings, adminstration, data for peer support contacts including number of contacts, time spent, mode of support (telephone or message) with women to determine uptake of the support component of the intervention
3.2. A short questionnaire survey of health workers providing or managing care and services to women after stillbirth or neonatal death at the included facilities but not directly involved in delivering the intervention will be conducted at the end of phase 2
4. Psychological assessments: women participants complete a questionnaire prior to the interview at 6-8 weeks after the birth including the following self-report tools:
4.1. The Edinburgh Postnatal Depression Score (EPDS) 10-item tool developed to assess depressive symptoms for postnatal use and since validated for use to identify anxiety and depressive symptoms in pregnancy
4.2. The Perinatal Grief Scale (PGS) a 33- item measure specifically designed to assess perinatal grief
5. Health economics: data will be captured to identify the key resources associated with the intervention, including:
5.1. Human resources: the intervention log as described above will be used to identify person (bereavement champions and peer supporters) time spent attending: trainings, meetings, adminstration, travel, and support
5.2. Equipment: a record will be kept of the number of mobile phones provided to peer support workers; health workers will be asked structured questions during their interview about any additional equipment required to improve care following baby loss
5.3. Out-of-pocket expenses: women and partners/family members will be asked structured questions during their interview about any out-of-pocket expenses incurred related to the intervention e.g. cost of sending text-based messages to peer supporters, travel etc

Overall study start date
01/08/2019

Completion date
31/07/2021

Eligibility

Key inclusion criteria
Postnatal women:
1. In the immediate postnatal period
2. Baby was stillborn (baby born at or after 28 weeks gestation with no signs of life) or died soon after birth in the facility (early neonatal death 0-6 days]) during one of the two identified recruitment periods in phase 1 and 2
3. Aged 18 years or over, at the time of recruitment

Partners and family members:
1. Of women consented to take part in the study; they will approached via the woman after she

has agreed (a partner's unwillingness to participate will not affect the woman's continued participation)
2. Aged 18 years or over, at the time of recruitment

Health workers (midwives, nurses, doctors and support staff) and peer supporters:
1. Directly involved in the delivery of the study intervention or who provide care or services to women after stillbirth in facilities

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Women total sample up to 120 participants, acceptability interviews and survey: partners and family members up to 60, health workers up to 140

Total final enrolment
176

Key exclusion criteria
1. Unable to give consent
2. Multiple births only where one baby survived the early neonatal period

Date of first enrolment
01/12/2019

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
Kenya

Uganda

Study participating centre
College of Health Sciences, Makerere University
C/O China Uganda Friendship Hospital, Naguru
PO Box 20145
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Uganda
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Study participating centre
School of Nursing Sciences, University of Nairobi
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Sponsor type
University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of the study will be published in high-impact clinical journals (eg BJOG, BMC Pregnancy and Childbirth) with open-access where possible; costs are available to support this. The findings will also be presented at international multidisciplinary meetings including the LAMRN conference, GLOW conference and the International Stillbirth Alliance (ISA) meeting, International Confederation of Midwives triennial conference (ICM). The research team has established links with stakeholders. Using their combined experience in writing for service users and the public the researchers will produce material for the websites and social media. Feedback to participants and local stakeholders is of key importance; therefore the researchers will organise a local dissemination workshop in month 12. Participants, families, clinical staff, operational managers and stakeholders including support groups will be invited to attend. A lay summary of findings will also be sent to all participants. Service-user members of the community engagement groups will be offered the opportunity and support to contribute to dissemination if they are willing. These activities will ensure that potential beneficiaries can engage with the study progress and findings. The overall aim is to increase awareness of the topic, application of the findings in clinical practice and reduction of the likelihood of duplication minimising future costs and burdens to funders and health systems.

Study members (those listed in this protocol and data collectors) will adhere to the following:
1. No raw data can be shared with anyone outside the core team prior to publication
2. Hard copy or electronic copies of any results cannot be disseminated beyond the immediate research team prior to publication
3. Results cannot be disseminated (written or oral) to external audiences without approval from the NIHR; this can be done through the Manchester team but requires 3 weeks' notice
4. Any press releases should be notified to the NIHR 14 days in advance of them happening
5. All publications should have a statement outlining how the data can be accessed
6. All publications should be submitted no later than 1 year after the project finishes and must contain the statement below:
"This research was commissioned by the National Institute of Health Research using Official Development Assistance (ODA) funding. The view expressed in the publication are those of the author(s) and not necessarily those of the NHS, the National Institute of Health Research or the Department of Health".

Additionally, the researchers will adhere to the International Guidelines: http://www.icmje.org /recommendations/browse/roles-and-responsibilities/ defining-the-role-of-authors-and-contributors.html

Additional documents will be available from the study contact by request.

Intention to publish date
30/11/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Tina Lavender (tina.lavender@manchester.ac.uk). Type of data: anonymised quantitative and qualitative. Available following the full publication of findings and for 5 years following completion and publication of results.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	24/07/2019	05/10/2022	No	No