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Improving perinatal bereavement support in Kenya and Uganda

Submission date
28/11/2023

Recruitment status
No longer recruiting

Registration date
08/12/2023

Overall study status
Completed

Last Edited
11/06/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The death of a baby before, during or soon after birth, termed stillbirth or neonatal death, is amongst the most traumatic of life events for parents. The overwhelming majority of stillbirths and neonatal deaths happen in low- and middle-income countries, with sub-Saharan Africa and South Asia accounting for around 75% of the global total. The death of a baby has long-lasting impacts on parents, greatly increasing the risk of poor mental and physical health and family breakdown, which has broad-ranging negative effects on wider society. When a baby dies, having good care and support from health workers in the hours and days surrounding the death has a positive effect in helping mothers and fathers cope, and adjust to the loss. However, in many countries parents do not always get good enough care or support after their baby dies. Finding better ways to support parents after the death of a baby is recognised by policymakers as a priority for research.
The NIHR Global Health Research Unit, a partnership between researchers in Africa, South Asia and the UK working with local experts and bereaved parents in Kenya and Uganda has developed changes to care, known as 'interventions' to improve support for parents. Previous studies have demonstrated that these interventions can be put into practice and that it would be possible to conduct further research to see whether they improve care and outcomes for women whose baby has died, and their families. In this study, the researchers in Kenya and Uganda, working with the UK team will conduct a trial across maternity hospitals in six areas of Kenya and Uganda involving around 800 women whose baby has died.

Who can participate?
Women aged over 16 years, birthed or received in-patient postnatal care in the included facility where the outcome was stillbirth or neonatal death

What does the study involve?
The study intervention includes an educational workshop for midwives, nurses, and doctors, setting up of a group of 'bereavement champion' health workers who will help improve care in hospitals and, in some sites, offering women access to peer support after discharge from hospital. All the hospitals will start the research providing the existing care, changes will be introduced after a few weeks or months. It is hoped that these changes will lead to better services and experiences for mothers, fathers, and their families. To know whether this is true,

the researchers will assess grief (the natural reaction to loss) in mothers taking part, also their mood and other emotions such as anxiety about 8 weeks after the birth. The study will also look at the resources and cost of the changes and how they are introduced and work in practice.

What are the possible benefits and risks of participating?
The study will demonstrate whether the changes work as intended and provide important information to help with future implementation in similar hospitals and communities.

Where is the study run from?
Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
June 2023 to May 2025

Who is funding the study?
National Institute of Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Tracey Mills, tracey.mills@lstmed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
LSTM 23-013

Study information

Scientific Title
Evaluation of a multicomponent intervention to improve perinatal bereavement support for women and families after stillbirth and neonatal death in Kenya and Uganda: a pragmatic cluster randomized controlled trial

Study objectives

The Improving Perinatal Bereavement Support (Kenya and Uganda) trial is a pragmatic multicentre stepped wedge cluster randomised controlled trial with a nested individually randomised two-arm sub-study. This trial will test the hypothesis that the implementation of a co-produced multicomponent intervention, which includes an educational workshop for health workers, the creation of a bereavement champion network and/or access to telephone peer support, will reduce grief intensity for women after a stillbirth or early neonatal death compared with existing care and support in Kenya and Uganda.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 02/05/2023, LSTM Research Ethics Committee (Pembroke Place, Liverpool, L3 5QA, United Kingdom; +44 (0)1517053100; lstmrec@lstmed.ac.uk), ref: 23-013

2. Approved 28/07/2023, Kenyatta National Hospital - University of Nairobi ERC (PO Box 20723, Nairobi, 00202, Kenya; +254 (0)2726300 ext 44102 or +254 (0)799495829; uonknh_erc@uonbi.ac.ke), ref: P519/O6/2023

3. Approved 12/09/2023, Makerere University (PO Box 7072, Kampala, 7072, Uganda; +256 (0) 200903786; healthsciences.irb@gmail.com), ref: MAKSHSREC-2023-538

Primary study design
Interventional

Study design
Pragmatic stepped wedge cluster randomized controlled trial with nested sub-study

Study type(s)
Other

Health condition(s) or problem(s) studied
Perinatal bereavement support

Interventions
This trial is a stepped-wedge cluster randomized controlled trial (of six clusters, three in each country), where the order of cross-over from usual care to intervention was determined in advance during a public randomisation process. The public randomisation meeting was conducted on 14/09/2023 via TEAMs simultaneously with LSTM (UK), University of Nairobi (Kenya) and Makerere University (Uganda) and coordinated by the LSTM Global Health Trials Unit (GHTU). Representatives from each study cluster attended with members of the research team. A minimisation approach with random elements was taken to ensure balance in allocation between countries. The country to start the trial first was determined by an independent LSTM staff member drawing a marked ball from an opaque bag labelled with each country initial. In each country, three cluster representatives selected a paper slip marked 1, 2 or 3 from an opaque bag to determine the order each representative would draw their site allocation ball. The first representative then drew a marked ball (numbered 1, 2 and 3) from an opaque bag to determine the position of their site. This was followed by representative 2 and 3 in turn for each country. The draw results were recorded and confirmed with all process participants at the conclusion of the draw. The clusters will cross over from usual care to the intervention phase at 6-weekly intervals with a 6-week cross-over period to allow clusters to prepare for the

introduction of the intervention. Women will be recruited to the trial approximately 2 weeks post-birth and will be followed up at 8-12 weeks, so their duration on the trial will be a minimum of 6 weeks (maximum 10 weeks) in total.

The nested sub-study will take place in two clusters (one in each country) as determined in the public randomisation process, where women will be invited to take part in the nested sub-study, and if consented, will be individually randomized at study recruitment to usual care or the intervention component, the offer of postnatal telephone peer support until 8 weeks postnatal. Women will remain in the sub-study for 6 weeks (minimum) to 10 weeks (maximum) in total. Participants will be individually randomized in the sub-study by the research assistant via web log-in to REDCap, based on a computer-generated sequence.

The main study intervention consists of the Advancing Bereavement Care (ABC) 2-day educational workshop designed for delivery to health workers, plus the Bereavement Champions network, a group of health workers committed to improving perinatal bereavement support for women and families. Following workshop training, Bereavement Champions will stimulate interest and support improvements and behaviour change opportunities. In addition to these components, a nested sub-study will see participants in two clusters (one in each country) individually randomised to usual postnatal and community care or usual care plus the offer of telephone peer support. Peer Supporters will be women who have had previous lived experience of the death of a baby (stillbirth or neonatal death) and have attended a training workshop and completed a peer support agreement.

There will be a mixed methods process evaluation study conducted in parallel with the main trial, consisting of observations, interviews and focus groups, and a cost-effectiveness health economic analysis.

Intervention Type
Mixed

Primary outcome(s)
Maternal grief intensity measured using a Kiswahili or Luganda version of the Perinatal Grief Intensity Scale (PGIS) at 8-12 weeks after birth

Key secondary outcome(s)
4. Psychological and social secondary outcomes include:
4.1. Maternal anxiety measured using the Generalised Anxiety Disorder 7-item scale (GAD-7) at 8-12 weeks after birth
4.2. Maternal postpartum depression measured using the Edinburgh Postnatal Depression Scale (EPDS) at 8-12 weeks after birth
4.3. Diagnosis and treatment of maternal mental health conditions measured using the maternal self-report method at 8-12 weeks after birth
4.4. Maternal perception of social support measured using the Multidimensional Scale of Perceived Social Support (MPSS) at 8-12 weeks after birth

Health economics secondary outcome:
Cost-effectiveness of the intervention measured using cost consequence framework at the study end

Process evaluation secondary outcomes include:
1. Fidelity, ‘dose’, reach and adaptations made in the study context measured using intervention

logs, observation checklists and peer support logs collated during the course of the trial
2. Women's, families', health workers' and service managers' views and experiences of the intervention and usual care after stillbirth and neonatal death, measured using qualitative interviews and focus group discussions conducted with participants during the intervention period until the end of the study
3. Factors influencing future scale-up and sustainability of the intervention, measured using intervention and site logs, minutes of bereavement champion meetings, peer support logs, plus complementary qualitative data from interviews and focus group discussions during the course of the trial.

Completion date
07/05/2025

Eligibility

Key inclusion criteria
1. Women, birthed or received in-patient postnatal care in the included facility where the outcome was stillbirth or neonatal death:
1.1. Stillbirth (antenatal or intrapartum fetal death ≥28 weeks' gestation or national definition)
1.2. Neonatal death (live birth at any gestation, baby(ies) died up to 28 days following birth in the facility
2. Over 16 years* at the time of recruitment
3. Able to speak Luganda, English or Kiswahili
*Whilst 18 years is the age of majority, women over 16 years old who are pregnant, married, have a child or cater for their own livelihood are considered emancipated minors for the purposes of research

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
Female

Total final enrolment
840

Key exclusion criteria
Women who had a multiple birth, where one baby was liveborn and is still living

Date of first enrolment
26/02/2024

Date of final enrolment
12/02/2025

Locations

Countries of recruitment
Kenya

Uganda

Study participating centre
Makerere University
Department of Nursing
Makerere University College of Health Sciences
Kampala
Uganda
PO Box 7072

Study participating centre
KAVI Clinical Research Centre
KAVI Institute of Clinical Research
University of Nairobi
Kenyatta National Hospital
Nairobi
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PO Box 19676-00202

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research (NIHR Global Health Unit on Stillbirth and Neonatal Death Prevention ad Management in SSA and SA)

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Tracey Mills (tracey.mills@lstmed.ac.uk).
The type of data that will be shared: Data will be provided in any open format (i.e. pdf, csv, r, stata etc.) using secure transfer methods i.e SSH portal secure end-to-end transfer or file encryption (AES 256-bit encryption), shared keys to be transferred separately to datasets.
Dates of availability: Data will be published on a compliant data-sharing site such as Clinical Study Data Request (CSDR) once analyses have been completed for publication.
Whether consent from participants was required and obtained: Participants give informed written consent that any anonymised data collected may be shared with researchers at other institutions.
Comments on data anonymization: A statistician will confirm any exclusions required (i.e. excluded data, anonymization).

IPD sharing plan summary
Available on request