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Feasibility of a co-produced intervention to improve support after stillbirth and neonatal death in India and Pakistan

Submission date
23/09/2022

Recruitment status
No longer recruiting

Registration date
19/10/2022

Overall study status
Completed

Last Edited
17/10/2022

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
Globally, 2 million babies were stillborn and 2.4 million died shortly after birth in 2019. Around 98% of these perinatal deaths occur in low and middle income countries (LMICs), with Sub-Saharan Africa and South Asia bear over 75% of the total. Despite some recent improvements, India and Pakistan account for amongst the highest burden in numbers of stillbirths and neonatal deaths globally. The death of a baby before or soon after birth is a traumatic event for parents, families, and communities, long-lasting grief and psychological distress are common for bereaved parents and their families. Lack of compassionate support immediately after the birth in hospital and in communities is an important factor associated with poor mental health outcomes for parents. In previous work to improve bereavement support in Kenya and Uganda, interventions to improve health worker knowledge and skills, hospital care and social support in the early postnatal period were developed, successfully implemented and feasibility tested. Similar interventions are likely to have the potential to improve bereavement care in India and Pakistan. The aim of this study is to assess a context-specific intervention developed with local stakeholders and communities to improve early bereavement care and support for women and families in India and Pakistan.

Who can participate?
1. Women aged over 18 years who have experienced stillbirth (baby born at or after 28 weeks gestation with no signs of life) or an early neonatal death (live birth, died 0-6 days before discharge) in the included facilities.
2. Partners, family members and friends aged over 18 years
3. Midwives/nurses, doctors, support staff and others who provide care or services to women after stillbirth in facilities

What does the study involve?
In this study, the co-produced intervention will be implemented in two hospitals in India and Pakistan. Individual components will be offered to women in the postnatal period who have experienced the death of a baby in the study hospitals. This group will be compared with a group of women receiving usual care after stillbirth or neonatal death in the same facilities,

immediately before the change being made. The main outcome will be to determine whether women are willing to take part and continue in the research until it is completed. The study will also assess whether the intervention can be implemented as planned, whether it is acceptable to women, families and health workers staff and potential ways to assess its effects on care and outcomes. If the study is successful, the research team will plan a larger study and seek more funding to carry this out.

What are the possible benefits and risks of participating?
The death of a baby before or shortly after birth is an extremely sensitive area of maternity care with the potential for women, partners, families and health workers participating in research to experience emotional distress when recalling difficult or traumatic events related to the death of their baby. To ensure that study is conducted appropriately, all recruitment processes, participant information and interview topic guides will be produced with input from our established community-engagement groups of local parents with experience in perinatal bereavement. A study-specific distress policy will be available and followed at all times, researchers assistants will have the necessary skills and experience to conduct the research sensitively.

Where is the study run from?
The study is led by the Liverpool School of Tropical Medicine (LSTM) in the UK and the partner country sites in Pakistan (Pakistan Institute for Living and Learning) and India (Bangalore Medical College and Research Institute) where the data will be collected.

When is the study starting and how long is it expected to run for?
October 2022 to December 2023

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

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

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
22 - 008

Study information

Scientific Title
Development and feasibility of a multi-component intervention to improve bereavement support after stillbirth and neonatal death in India and Pakistan

Study objectives
To explore the acceptability, implementation, recruitment, and retention of women offered the intervention in India and Pakistan settings

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/09/2022, LSTM Research Ethics Committee (Research Governance and Ethics Office, Room 221, 2nd Floor LLSA, Daulby Street, Liverpool, L3 5QA, United Kingdom; +44 151 702 9396; Denise.Watson@lstmed.ac.uk), no ref number

Study design
Mixed methods development/adaptation and feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Stillbirth or neonatal death in current pregnancy

Interventions
A pre and post cohort design, over 14 months, will be conducted to allow implementation of the intervention in one site in each country and assessment of the feasibility of a full-scale effectiveness evaluation. During the recruitment periods as many eligible women meeting the inclusion critieria as possible will be approached. The researchers will aim to recruit up to 40-60 women per country (total sample 80-120), who have experienced a stillbirth or neonatal death in the index pregnancy, to assess the feasibility of data collection, explore experiences of the intervention and study participation. In the intervention period, partners, family members* or

friends* (* the key provider(s) of emotional support as defined by the woman) will be approached to take part where women agree, although it is recognised that not all will want to participate. Health workers and others delivering the intervention (up to 15 per country) will also be recruited to explore experiences of the intervention and participation in the research. All health workers involved in providing/managing care for women after stillbirth or neonatal death in the included facilities will be invited to complete a short questionnaire survey, at the end of the study, to assess experiences of the intervention and capture wider impacts of the research on practice.

Pre-intervention period (month 0 to 6 months):
In month 10-13 the researchers will recruit up to 30 women per country who have experienced a stillbirth or early neonatal death, currently having standard care in the included facilities. Women will be invited to complete follow-up questionnaires and qualitative interviews 6-8 weeks after discharge.

Intervention period (month 6 to 12 months):
The intervention will be introduced to both sites in month 17. The researchers will recruit a separate group of 30 women per site (as above) in month 18-21. Women will be offered any individually focused intervention components as appropriate (eg peer support). Follow-up questionnaires and qualitative interviews will be conducted 6-8 weeks after the birth.

Intervention Type
Behavioural

Primary outcome(s)
Recruitment and retention of women in the study, measured using the study screening and recruitment log at identification of each eligible participant, approach, recruitment and study completion, withdrawal or loss to follow up

Key secondary outcome(s))
1. Acceptability and uptake of the intervention and experiences of study processes, explored via semi-structured face-to-face or telephone interviews with the following groups:
1.1. Women participating in the study in n up to 120; up to 60 per country) at 6 -8 weeks after the birth
1.2. Partners and family members of women participating in the intervention period (N; up to 60; up to 30 per country) at 6-8 weeks after the birth
1.3. Health workers and others (e.g. parent peer supporters) involved in the delivery of the intervention (up to 30; up to 15 per country) in October – December 2023
2. Characteristics and acceptability of the proposed psychological measures assessed using:
2.1. The Edinburgh Postnatal Depression Score (EPDS) at 6-8 weeks post birth
2.2. The Perinatal Grief Intensity scale (PGS) at 6-8 weeks post birth

Completion date
30/12/2023

Eligibility

Key inclusion criteria
Women:
1. Immediate postnatal period
2. Experienced stillbirth (baby born at or after 28 weeks gestation with no signs of life) or early

neonatal death (live birth, died 0-6 days before discharge) in the included facilities, within the study recruitment periods
3. Over 18 years at time of recruitment

Partners/family members/friends:
1. Identified by women consented to take part in the study during the intervention period only; they will be approached via the woman after she has agreed (a partner's etc unwillingness to participate will not affect the woman's continued
participation)
2. Aged 18 years or over, at the time of recruitment

Health workers:
1. Midwives/nurses, doctors, support staff and others directly involved in the delivery of the study intervention or who provide care or services to women after stillbirth in facilities.
2. Survey only: Health workers involved providing or managing maternity or neonatal services, but not previously directly involved in the research

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Women who are unable to give consent
2. Multiple births only where one baby survived the early neonatal period (women)

Date of first enrolment
01/12/2022

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
India

Pakistan

Study participating centre
Bangalore Medical College
Fort, Krishna Rajendra Rd
Karnataka
Bengaluru
India
560002

Study participating centre
Liquat University of Medical and Health Sciences
Sindh
Jamshoro
Pakistan
76090

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

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 are/will be available upon request from Prof. Tina Lavender (tina.lavender@lstmed.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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes