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Development and feasibility of a co-produced intervention to enhance parental involvement in facility neonatal care in India, Pakistan and Tanzania

Submission date
03/08/2022

Recruitment status
No longer recruiting

Registration date
12/08/2022

Overall study status
Completed

Last Edited
12/12/2024

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

In recent decades improvements in neonatal care (NNC) have reduced the numbers of babies born early or who are sick at birth dying soon after birth around the world. However, babies born small or sick in sub-Saharan Africa or South Asia are still much more likely to die than babies born in high income countries (HICs). Babies needing neonatal care after birth are usually separated from their parents with most of the care being provided by health workers and this is known to have negative impacts on physical, psychological, and emotional health of both parents and infants. Following the philosophy of family- centred care, new ways of caring for babes in NNU in HIC have been developed where parents are encouraged to become more actively involved in the care of their baby. In some countries this approach has been developed so that parents receive education and support and are able to provide much of the care the baby needs with help from neonatal nurses and doctors. Research has shown that increased involvement can help improve the baby's health including weight gain and reduce the chance of infection in hospital. Mothers who were involved also experienced less stress and anxiety.

Increasing parents' involvement in NNC could also improve outcomes for babies and parents in sub–Saharan Africa and South Asia, however differences in the way care is provided, lack of resources, social and cultural differences mean that strategies used in other settings might not be workable or effective. Research is needed to understand more about current care and parents' experiences and develop a specific intervention for these settings.

In this study in hospitals in India, Pakistan and Tanzania, we will explore the experiences of parents whose baby was in NNU and health workers who regularly provide care to understand needs and the barriers and facilitators to change. Working with local parents, health workers and managers we will use this information along with previous research on the same topic to agree a new package to improve partnerships with parents in neonatal care, this could include education, a more welcome environment and emotional support. We will then assess whether it is possible to conduct research to test the package by introducing the change with a small number of parents and babies whilst they are in the NNU within hospitals in these three countries. We 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 services. If this is study is successful, we will seek funding for a larger study to assess whether this change would benefit babies and parents and families, represents good value for money and should be introduced across similar settings.

Who can participate?
Mother and babies who are cared for the in neonatal unit of the included sites in India, Pakistan or Tanzania for at least 7 days, family members and health workers involved in delivery of the study intervention

What does the study involve?
In phase 1 (usual care) participants will be asked for permission to collect details about their maternity care and the baby's care in hospital, they will meet with the research assistant 3 times (at recruitment, before baby is discharged and 6-8 weeks after discharge to collect data and complete questionnaires. In phase 2, in addition participants will be offered the study intervention (to be confirmed) and invited to an interview completed at the 6-8 week data collection visits. Family members of participants in phase 2 (intervention phase) and health workers will be invited to participate in an interview at the end of the study

What are the possible benefits and risks of participating?
The study is not intended to directly benefit participants, we hope the study intervention might help women and families participating in phase 2 feel better supported, but cannot guarantee this will be the case. Discussing events related to the birth of a small and or sick baby could cause distress to parents, but the researchers are trained to provide support. The information we get will help to improve the care of small and sick babies in the future.

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?
April 2022 to December 2025

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

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

Contact information

Type(s)
Public

Contact name
Dr Tracey Mills

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
22-009

Study information

Scientific Title
Enhancing parental involvement in the care of sick neonates in India, Pakistan and Tanzania: A Participatory Action Research Study

Study objectives
To explore the potential of parent partnerships in facility neonatal care to improve outcomes for small and sick newborns

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/07/2022, Liverpool School Tropical Medicine REC Committee (Pembroke Place, Liverpool, L3 5QA, UK; +44(0)151 705 3100; lstmrec@lstmed.ac.uk), ref: 22-009
2. Approved 20/05/2022, Catholic University of Health and Allied Sciences (CUHAS, Bugando, CUHAS Ethical Committee, Mwanza, Tanzania PO BOX 1464; +255282983384; VC@bugando.ac.tz), ref: 22-009

Study design
Mixed methods feasibility study conducted in two sites

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied

Parent partnerships in facility neonatal care to improve outcomes for small and sick newborns

Interventions
A co-production process will be initiated involving representatives from NIHR Unit stakeholders (including local clinicians, policy makers and community leaders) and Community Engagement Groups of local parents with previous experience of neonatal care, in each site. The findings from the literature review and exploratory study will be presented at an in-person meeting, or a virtual meeting if travel is restricted. A series of follow-on meetings will be convened in each site to identify potential intervention components based on priorities identified during the phase 1. Intervention design will be guided by the philosophy of family-centred care which emphasises involvement of parents in their child's medical care in partnership with health workers through principles of dignity and respect, information sharing, participation, and collaboration. Currently there is insufficient evidence from LMIC settings including Africa and Asia to guide the content of the intervention/model.
However, in HIC settings the Family Integrated Care (FIC) model has actioned these principles integrating parents into neonatal care using a 'four pillar' approach with activities to support each component. Some or all these components may be considered for the model(s), but in keeping with PAR, the final decision will be made by the site groups. A 'learning and sharing event' in month 21, will bring representatives of all three countries together in person (or virtually if required) to share experiences in the co-production process and finalise implementation strategies incorporating the Behaviour Change Wheel, and human-centred design which will aid us in embedding human perspectives and empathy in the intervention components

Intervention Type
Behavioural

Primary outcome(s)
Recruitment and retention of mothers (caregivers) and babies in the study. Recruitment and retention is 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 of the intervention, research and study processes for parents and health workers is assessed using qualitative interviews conducted at the end of the intervention phase, 6-8 weeks following discharge (parents) and at the end of the intervention phase (health workers directly involved in the delivery of the intervention) and a survey questionnaire for all neonatal and maternity staff providing newborn care
2. Characteristics and acceptability of the proposed psychological measures is assessed with mothers/caregivers recruited to the study at the following time points:
2.1. Parental stressor scale: Neonatal intensive care unit (PSS:NICU; measures parental anxiety and stress) baseline (recruitment), immediately prior to baby's discharge from NNU, 6-8 weeks following discharge
2.2. Edinburgh postnatal depression scale: (assesses depressive symptoms in the postnatal period EPDS) baseline (recruitment), immediately prior to baby's discharge from NNU, 6-8 weeks following discharge

Completion date
30/06/2025

Eligibility

Key inclusion criteria
Mother/Caregiver/baby pairs
1. Baby admitted to NNU and expected to remain for >7 days
2. Mother (caregiver) willing to commit to the study intervention (intervention phase only)
3. Mother (caregiver) over 18 years at recruitment

Partner/Family member
1. Partner or family member of mother (or caregiver).
2. Over 18 years old at time of recruitment

Health workers, service managers, peer supporters
1. Nurses, midwives, doctors directly involved in the delivery of the intervention
2. Peer supporters (parents with prior lived experience) if involved in delivery of the intervention

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Multiple births where one only baby received NN care and/or is still living
2. Baby receiving palliative care
3. Baby critically ill (e.g receiving ventilatory/ organ support and/or not expected to survive)
4. Severe congenital abnormality

Date of first enrolment
01/10/2023

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
India

Pakistan

Tanzania

Study participating centre
Karnataka Medical College
Hubbali
Karnataka State
Hubbali
India
580020

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

Study participating centre
Bugando Medical Centre
PO BOX 1370
Mwanza
Tanzania
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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