ISRCTN51636372 https://doi.org/10.1186/ISRCTN51636372

Impact of a family-centered discharge and follow up programme on survival, growth, and development of high-risk newborns discharged from a neonatal unit in Kiwoko, Central Uganda

Submission date
02/03/2020

Recruitment status
No longer recruiting

Registration date
09/03/2020

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Neonatal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Despite the increasing development of neonatal units in low-resource settings, very few follow-up programmes exist to ensure these high-risk infants receive the on-going care needed upon discharge from the hospital. Follow-up care is critical because it can help detect feeding difficulties that can lead to stunting, wasting or failure to thrive. Follow-up can also be a vehicle for early identification of neurodevelopmental delays. Comprehensive, locally appropriate and well-functioning follow-up programmes for newborns discharged from neonatal units in LMICs are needed if the researchers are to see these infants survive and thrive.
The Hospital to Home programme, developed and piloted jointly by Adara Group and Kiwoko Hospital, is designed to improve both the care of sick and premature babies in the hospital as well as provide follow up support after discharge. The package consists of two parts. The first part takes place in the hospital and includes improved processes for discharge from the newborn care unit; training and education for staff in supporting mothers to breastfeed their baby and in providing care that supports optimal brain development; an education programme for the parents in the provision of at-home care for their high-risk babies - including the recognition of danger signs. The second part of the package takes place in the community and helps ensure that the baby continues to receive follow up care after discharge. An outreach of highly trained Village Health Teams (VHTs) conduct home visits and provide support to high-risk newborns and their caregivers during the first six months after discharge. The study team is primarily interested in feasibility, acceptability and potential for impact on the health and wellbeing of the child and their caregivers.
This study aims to investigate the feasibility, acceptability, scalability of the Hospital to Home programme.

Who can participate?
Babies born in Kiwoko Hospital during the study period, their parents/caregivers, and village health teams.

What does the study involve?
The study team will use a mixed-methods approach to evaluate the feasibility and acceptability of the programme, potential impact, and also evaluate the facilitators and barriers to scale-up. To evaluate early indication of impact, the researchers will examine infant growth, rates of exclusive breastfeeding, neurodevelopment, and caregiver-child bonding with a historical comparison cohort compared to an intervention cohort. Eligibility includes those infants discharged from Kiwoko Hospital neonatal unit and living in the three surrounding districts: Nakaseke, Nakasongola and Luwero), born July-September 2018 (historical comparison) or July-September 2019 (intervention comparison). The historical comparison group will have received usual neonatal care from KH while the intervention group will have also received facility-based interventions such as lactation and breastfeeding support, neonatal physiotherapy, discharge education to the parents/caregivers, and at-home follow up visits conducted by Hospital to Home Village Health Teams (VHTs; Uganda's term for Community Health Workers) trained in the care of high-risk newborns for a duration of six months post-discharge. When eligible, these patients will be called and provided with a description of the study. If they are interested, they will travel to Kiwoko Hospital. At the hospital they will go through the informed consent process. If they consent, then Adara will complete all assessments on that day and no additional research activities will be requested of the participants.

What are the possible benefits and risks of participating?
The researchers believe this study to be low risk and believe that the benefits for this population far outweigh the minor risks to the study participants. Benefits for parents of the infants include education about at-home care, referral needs and follow up care of babies. Their babies will receive follow up visits from trained VHTs. Mothers of the deceased infants who participate in the incident review could experience some mental stress, for which the researchers have trained local research nurse to communicate with these parents using bereavement message.

Where is the study run from?
Kiwoko Hospital (Uganda)

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

Who is funding the study?
Grand Challenges Canada

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
629

Study information

Scientific Title
A quasi-experimental pilot feasibility trial to assess the feasibility, acceptability and early effectiveness of the Hospital to Home Programme (H2H), designed for follow up of high-risk newborns discharged from the Kiwoko Hospital neonatal unit, Central Uganda

Acronym
H2H

Study objectives
A family-centred discharge and follow-up programme is feasible, acceptable and has potential positive impacts on the health and wellbeing of high-risk newborns and their caregivers during their NICU stay and following discharge from the Kiwoko Hospital neonatal unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/11/2018, Higher Degrees, Research & Ethics Committee, Makerere University School of Public Health (College of Health Sciences, School of Public Health Higher Degrees, Research and Ethics Committee, Makerere University, PO Box. 7072 Kampala, Uganda; +256 414 532207; no email provided), ref: 629
2. Approved 20/12/2018, Uganda National Council for Science and Technology (UNCST) (Plot 6 Kimera Rd, Kampala P.O. BOX 6884, Uganda; no tel. provided; no email provided), ref: HS292ES
Reference number: HS292ES

Study design
Quasi-experimental with historical comparison group

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
High-risk newborns

Interventions
The Hospital to Home programme, developed and piloted jointly by Adara Group and Kiwoko Hospital, is designed to improve both the care of sick and premature babies in the hospital as well as provide follow up support after discharge. The package consists of two parts.

The first part takes place in the hospital and includes improved processes for discharge from the newborn care unit; training and education for staff in supporting mothers to breastfeed their baby and in providing care that supports optimal brain development; an education programme for the parents in the provision of at-home care for their high-risk babies - including the recognition of danger signs.

The second part of the package takes place in the community and helps ensure that the baby continues to receive follow up care after discharge. An outreach of highly trained Village Health Teams (VHTs) conduct home visits and provide support to high-risk newborns and their caregivers during the first six months after discharge.

The study team is primarily interested in feasibility, acceptability and potential for impact on the health and wellbeing of the child and their caregivers. To evaluate the programme, the researchers will compare the assessment of the babies' growth and neurodevelopmental status before and after the initiation of the H2H programme. A historical group of babies – or those who did not receive H2H intervention will be compared to an intervention group of babies – or those that did receive the H2H intervention.

Qualitative Data Collection
Participants: Parents/caregivers, VHTs, and hospital staff
To assess programme feasibility and acceptability we will be collecting data through IDIs. A qualitative expert will be conducting these interviews. We will use a semi-structured interview guide as tool to elicit feedback from the participants (parents/caregivers, VHTs, and hospital staff) and will provide opportunity for additional comments. After consenting the participants, staff will audio record the IDIs for transcription and possible translation.

Quantitative Data Collection:
Participants: Infants
Data will be collected to assess feasibility and acceptability and also preliminary effectiveness. Assessment of the babies in both control and intervention cohorts will be done at only one point of time---at six months adjusted age. After each infant is consented, we will use standardised tools to assess anthropometrics, neurodevelopment, and parent-child attachment (growth charts, Griffiths Mental Development Scales (GMDS), Maternal Infant Responsiveness Instrument (MIRI)). We will collect socio-demographic characteristics and history through an Intake Form and History Form which are adapted from forms used in the ABAaNA study (see a protocol published about the study in https://bmjopen.bmj.com/content/9/10/e032705?rss=1) on which Adara Development and Kiwoko Hospital are collaborators. Trained assessors from Kiwoko Hospital will collect data on GMDS, MIRI and anthropometrics. Data will also be used from the patients' hospital records. These data are collected during the patient's hospital stay related to their diagnosis and treatment.
If an infant death occurs among the babies discharged from Kiwoko neonatal unit, the research nurse will consent the parent and collect relevant information about cause of death using the Critical Incident Review form.
Participants: VHTs
To evaluate the impact of the VHT training, a quantitative pre- and post-course test of knowledge will be administered to all H2H VHTs (n=100) based on the training curriculum. Adara' s RMEO and a research nurse (community) and VHT trainers will collect knowledge test data before and after the training and every quarter until September 2020. A skills test will be conducted by the community midwife on a subset of the VHTs. The research nurse will visit randomly selected VHTs and observe their skills using skill assessment form.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility, acceptability, scalability of H2H package:
1. Participant recruitment rate will be recorded as the number of caregivers/parents who consent to participate in the study by the end of May 2019 (caregivers in control cohort) and May 2020 (caregivers in intervention cohort)
2. Number of parents/caregivers discharged following the discharge checklist will be measured as the number of caregivers recorded by KH discharge coordinators by the end of September 2020
3. Number/proportion of neonatal unit in-hospital follow-up appointment attendance will be measured as the number recorded in follow up clinic's registry by the end of September 2020
4. Number/proportion of babies followed up by VHTs will be measured as the number recorded by VHTs in VHT register by the end of September 2020
5. Number of VHTs attending monthly meetings and their knowledge retention will be measured as number/proportion recorded during those meetings, which will be continued until the end of September 2020

6. VHTs' performance/skill in delivering at-home newborn care will be measured by observing their records of a baby's assessment (e.g. weighing, temperature reading, weight classification, neonatal unit follow up/referral need etc) against assessment of the same baby by an experienced midwife
7. Barriers and challenges experienced in receiving health care, follow up, and comments about the acceptance of the neonatal unit and VHT care will be examined by views and experience of caregivers and VHTs in IDIs to be conducted by the end of September 2020
8. The operational feasibility of continuing H2H implementation and potential to sustain the intervention by KH will be assessed by the views and experience of KH neonatal unit staff, VHTs and Adara staff in their IDIs to be conducted by the end of September 2020
9. The operational feasibility of recruiting skilled village health teams / community healthcare workers will be assessed by the views and experiences of KH neonatal unit staff and Adara staff in their IDIs to be conducted by the end of September 2020
10. Ability to seek appropriate care when needed will be measured as the number/proportion of babies referred by a VHT to health facility who went to the health facility as documented on the VHT register by the end of September 2020
11. The length of patient's stay in the neonatal unit will be measured as the average duration for all patients during the one year prior (01/04/2018 – 31/03/2019) and one year post (01/04/2019 – 31/03/2020) programme implementation, as documented in the patients' charts and corresponding neonatal unit database

Key secondary outcome(s))

Early effectiveness on growth and neurodevelopmental outcomes of high-risk newborns:
1. Anthropometrics (weight, height, head circumference, upper arm circumference and anaemia) will be measured using infant weighing scales, length board, MUAC tape, Paediatric circumference tape (head circumference), and HemoCue (anaemia) at six months adjusted age. Assessment will be completed by the end of May 2019 for the control cohort and May 2020 for the intervention cohort
2. Neurodevelopmental outcomes will be measured using Griffith Mental Development Scales questionnaire at six months adjusted age. Assessment will be done by the end of May 2019 for the control cohort and May 2020 for the intervention cohort
3. Mother-child bonding will be measured using Maternal Infant Responsiveness Instrument at 6 months adjusted age. Assessment will be done by the end of May 2019 for the control cohort and May 2020 for the intervention cohort
4. Exclusive breastfeeding rate at six months adjusted age will be measured as number recorded in the History Form. Assessment will be done by the end of May 2019 for the control cohort and May 2020 for the intervention cohort

Completion date

15/02/2021

Eligibility

Key inclusion criteria

1. Growth, neurodevelopmental assessment and caregiver-child bonding:
1.1. Born in a three-month window (July -Sept 2018 for historical comparison cohort and July-Sept 2020 for intervention cohort)
1.2. Discharged alive from the KH neonatal unit
1.3. 6 months adjusted age at time of assessment (infant may be one week younger or two weeks older than 6 months adjusted age at time of assessment)
1.4. Gestational age available

1.5. Living in 3 surrounding districts (Luweero, Nakaseke, Nakasongola)
1.6. Obtained informed written consent by guardian
2. Parents/caregiver interviews before H2H implementation: those parents/caregivers who will not receive the intervention and are a part of the historical control
3. Parents/caregiver interviews during/after H2H implementation: those parents/caregivers who have received the intervention and are part of the intervention group
4. Clinicians/nurses: those working in Kiwoko Neonatal Intensive Care Unit who have provided written consent
5. Village Health Teams: those who received Adara VHT training and are mobilized for H2H project and who have provided written consent

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
191

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2019

Date of final enrolment
15/02/2021

Locations

Countries of recruitment
Uganda

Study participating centre
Kiwoko Hospital
Luwero
Nakaseke District
Kiwoko
Uganda
P.O. Box 149

Sponsor information

Organisation
Adara Development

Funder(s)

Funder type
Government

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, gchallenges, Grand Challenges Canada / Grands Défis Canada, grandchallengescanada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/02/2025	13/02/2025	Yes	No
Protocol article		02/03/2021	14/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes