ISRCTN79723072 https://doi.org/10.1186/ISRCTN79723072

Birth complications and risk of developmental delays and disabilities for children in Nepal, and the possibilities of a family-centred intervention for the children and their caregivers

Submission date
25/01/2024

Recruitment status
No longer recruiting

Registration date
13/03/2024

Overall study status
Completed

Last Edited
11/03/2024

Condition category
Pregnancy and Childbirth

[ ] 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, there has been a lot of investment in neonatal care in low and middle-income countries, which has led to reduced mortality. But what the children's development looks like after they have survived is unclear, even though this is important information to be able to plan for health care and habilitation efforts. In many countries, there is a lack of support and habilitation for children with disabilities, which leads to poorer development and participation for the children. Families are often left alone to care for their children with disabilities, which creates a high risk for stress, isolation, depression and reduced quality of life. To include the children in care planning, there is a need for both information about risk factors for early targeted identification and prevention, as well as what interventions could benefit them. Family-centered intervention models that are affordable, accessible and adapted to the context of low-income settings have the potential to increase caregiver quality of life, improve access to services, and help children participate in daily life. An earlier study (Project 1) first determined the risk of developmental delays and disabilities for children in Nepal who had complications around the time of birth, compared to children who did not have complications. This study (Project 2) aims to develop and evaluate the feasibility of a family-centred intervention to increase participation for children with developmental delays and disabilities and the quality of life for their caregivers.

Who can participate?

Children aged 3-6 years old identified to have a developmental delay or disability in the project: Rapid Feedback for quality improvement in Neonatal rEsucitation (REFINE) and their families. Caregivers of children with different developmental delays and disabilities, children with special educational needs and disabilities, teachers and health workers and local leaders or influential people in the community.

What does the study involve?
This study includes two projects:
Project 1 is ongoing and the information is provided as background. The REFINE project included children born at the Pokhara Academy of Health Sciences hospital in Nepal from 2018-2020, who either had complications around the time of birth or no complications. The children have been followed up since birth, and their development have been assessed at 6, 12, 18 or 24 months using the Malawi Development Assessment Tool (MDAT), which is a tool developed for low and middle-income to identify children with developmental delays and disabilities. The children identified to have a developmental delay from MDAT were invited for a follow-up assessment by teams of medical doctors, data collectors and physiotherapists in the following domains; 1) gross and fine motor function 2) communication, speech and language 3) cognition, 4) behavior and 5) social function 6) epilepsy 7) hearing and 8) vision 9) other health conditions. The risk of developmental delay or disability was calculated if the child was born with or without complications.

This study, Project 2, will develop and test the feasibility of an intervention for children with developmental delays and disabilities and their families. The team have developed a first draft of the intervention which will be further developed and evaluated for feasibility through the following activities:
2.1. Qualitative in-depth interviews with caregivers
2.2. Piloting of planned intervention components and study tools; including a cross-sectional exploratory pilot study of the educational software Onecourse, with observations and assessments at two points in time, and pilot testing the tool Picture My Participation (PMP) to test acceptability and relevance.
2.3. Three participatory co-creation workshops with relevant stakeholders
2.4 Establishing a community advisory board that will sit regularly during the planned future intervention.

What are the possible risks and benefits of participating?
There are some expected benefits for the participants involved in the studies, such as professional specialized assessment, where they can have an opportunity to discuss the child's condition with a professional and receive information on referral and specialized services. Some caregivers might be included in the future planned intervention programme that will hopefully contribute to increased participation in daily life for children with disabilities, as well as improved quality of life for their caregivers. There are no kinds of activities that could be risky for participants, only assessments, questionnaires, workshops, piloting of tools and tablet applications, in-depth interviews and meetings.

Where is the study run from?
The study is a collaborative project between Uppsala University (Sweden) and Golden community (Nepal) and will run at the Golden community office, the Pokhara Academy of Health Sciences hospital, therapy clinics and communities in Pokhara, Nepal

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

Who is funding the study?
The Swedish Research Council (Sweden)

Who is the main contact:
1. Carin Andrews, carin.andrews@uu.se
2. Regina Gurung, rejina.gurung@uu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Carin Andrews

ORCID ID
https://orcid.org/0000-0002-9928-4423

Contact details
Akademiska sjukhuset
Uppsala
Sweden
751 85
+46184714710
carin.andrews@uu.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2022-04730

Study information

Scientific Title
Family-centred INtervention and Epidemiology of Developmental Delays and Disabilities in Kaski, Nepal (FINE-DDD)

Acronym
FINE-DDD

Study objectives
Children exposed to complications around the time of birth in Nepal have a higher risk of developmental delays and disabilities, as compared to children not exposed to complications around the time of birth. Through the use of participatory co-creation methods such as workshops, in combination with qualitative studies, piloting and a community advisory board we can develop a family-centred intervention for children with developmental delays and disabilities, that is acceptable, affordable, accessible and adapted to the context of Nepal.

Ethics approval required
Ethics approval required

Ethics approval(s)

1. Approved 13/07/2023, Nepal Health Research Council (Ramshah Path, Kathmandu, PO Box 7626, Nepal; +9771425220; nhrc@nhrc.gov.np), ref: 3862

2. Submitted 28/02/2024, The Swedish Ethical review authority (Box 2110, Uppsala, 750 02, Sweden; +46104750800; registrator@etikprovning.se), ref: Nil known

Primary study design
Interventional

Study design
Non-randomized intervention development and pilot feasibility testing

Study type(s)
Diagnostic, Quality of life, Screening, Treatment

Health condition(s) or problem(s) studied
Children with developmental delays and disabilities and their caregivers

Interventions
In brief, this study including:
1. A cross-sectional follow-up of a prospective cohort of children 3-5 years either exposed (cases) or unexposed (controls) to complications around the time of birth; the prospective mixed-methods cross-sectional follow-up study to REFINE is included as background
2. Development and feasibility testing of an intervention for children with developmental delays and disabilities in Nepal including;
2.1. Qualitative in-depth interviews
2.2. Piloting of planned intervention components and study tools
2.3. Participatory co-creation workshops
2.4. Establishment of a community advisory board.
All data will be collected in collaboration with the NGO Golden Community in Nepal.

Background: Project 1
This project will build on the Rapid Feedback for quality improvement in Neonatal rEsucitation (REFINE) project. The REFINE project included children born at the tertiary hospital Pokhara Academy of Health Sciences (PoAHS) in Nepal from 2018-2020, exposed (n=381) or unexposed (n=381) to complications around the time of birth. The children have been followed up since birth, and their development is being regularly assessed using tools developed for low and middle-income countries. The children screened positive in REFINE for developmental delays or disabilities from the Malawi Development Assessment Tool (MDAT) at 6, 12, 18 or 24 months will be invited for a follow-up assessment by teams of medical doctors, data collectors and physiotherapists in the following domains; 1) gross and fine motor function 2) communication, speech and language 3) cognition, 4) behavior and 5) social function 6) epilepsy 7) hearing and 8) vision 9) other health conditions. The risk of DDD in the unexposed or unexposed cohort will be calculated using the hazard ratio (HR).

Intervention development and pilot feasibility study: Project 2
In Project 2, an intervention for children with developmental delays and disabilities and their families will be developed and feasibility tested. A first draft of the intervention has been developed which will be further developed and evaluated for feasibility through the following activities:
1. Qualitative in-depth interviews with caregivers. The in-depth interview will be audio-recorded

and transcribed verbatim.
2. Piloting of planned intervention components and study tools; including a cross-sectional exploratory pilot study of the educational software Onecourse, with observations and assessments at two points in May 2024 with two weeks in between the assessments, and pilot testing the tool Picture My Participation (PMP) regarding acceptability, relevance and application for setting participation goals. The PMP pilot testing is done at one time point, where the interview-based tool will be used on caregivers and after that, they will be asked questions on their experience of using the tool, regarding i) acceptability ii) relevance and iii) application.
3. Three participatory co-creation workshops with relevant stakeholders
4. Establishing a community advisory board that will sit regularly during the planned future intervention.

Intervention Type
Mixed

Primary outcome(s)
The children's participation in everyday activities measured using the tool Picture My Participation (PMP), which will be piloted on 11 caregivers of children with a developmental delay or disability in this feasibility study using the interview-based tool at one timepoint

Key secondary outcome(s)
The in-depth interview will be audio-recorded and transcribed verbatim. The feasibility testing of one of the intervention components using the educational Software Onecourse will be done with 11 children and will include an assessment of the child’s performance level in literacy and numeracy using Onetest, a Video recording protocol of the child's interaction with the software, and questionnaires on attitudes towards learning and engagement with learning. The progress of the workshops and community advisory board will be documented using workshop/meeting notes and co-created documents. Observations and assessments will be undertaken at two points with two weeks in between the assessments.

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. In-depth interviews: purposefully selected caregivers of children with developmental delays or disabilities
2. Piloting study tools and educational apps: purposefully selected caregivers of children with developmental delays or disabilities.
3. Participatory co-creation workshops: purposefully sampled stakeholders such as caregivers, health workers and teachers
4. Community advisory board: purposefully sampled stakeholders such as caregivers, health workers and teachers

Participant type(s)
Patient, Health professional, Population, Service user

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
9 Years

Sex
All

Key exclusion criteria
Not meeting the inclusion criteria

Date of first enrolment
11/12/2023

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Nepal

Study participating centre
Golden community
Chakupat 15, Lalitpur, Nepal
Lalitpur
Nepal
44600

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Organisation

Funder(s)

Funder type
Government

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

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 Carin Andrews, carin.andrews@uu.se. Since this study includes personal data, we will keep the access available upon request only, and we will only share anonymized data.

The anonymized data used for scientific publications will, after publication, be made available upon request through open-source data depositories, in accordance with the FAIR principles. We will limit data access to be available upon request and with the approval of both principal investigators in the project. The data files will be accompanied by metadata including project proposals, detailed descriptions of methods used and definitions of variables.

Written informed consent will be sought from all participants in the studies. We will not use an assent form for the children since they will all be below 7 years of age.

Golden Community (GC) in Nepal are responsible for pseudonymizing the data as well as storing the code key. The code key will be stored on the secure server on GC and only the data manager will have access to the file. The retention of the code key during the course of the project is important because we will follow the same children in our different studies. The research team at Uppsala University will only have access to pseudonymised data from GC. Other co-researchers at other universities (if applicable) will only have access to anonymized data, i.e. data that does not have a code key and therefore cannot be traced back to participants.

Ethical approval for performing the data collection has been granted from the Nepal Health Research Council reference number 3862. Ethical approval for analysis of collected data in Sweden from Etikprövningsnämden is in progress.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes