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Improving early detection and intervention for young infants at high risk of neurodevelopmental delay and disability in Uganda

Submission date
22/11/2017

Recruitment status
No longer recruiting

Registration date
16/12/2017

Overall study status
Completed

Last Edited
03/10/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Common newborn conditions such as neonatal encephalopathy (birth asphyxia), prematurity, and infections can lead to disability. Having a child with a disability can have a major impact on families in any country but this may be more marked in low and middle income countries where support services are few and stigma more overt. There is growing evidence that early intervention programmes, which aim to enhance a child's development during infancy, have the potential to limit impairments following early brain injury, either directly or through their influence on the care-giving environment, and to improve circumstances for the child and their family. The study aims to evaluate the feasibility and acceptability of an early intervention programme in two Ugandan settings. It also aims to obtain preliminary data on whether the programme will be more effective than current standard care practices in improving the quality of life of infants with developmental disability and their caregivers.

Who can participate?
Infants aged 6-9 months who are diagnosed with moderate to severe neurodevelopmental impairment, and their caregivers.

What does the study involve?
Infants are randomly assigned to one of two groups. One group receives an early intervention package, which involves 10 group training sessions for caregivers delivered over a six-month period. In these sessions, groups of around 6-10 caregivers (and their families) participate in training covering positioning, feeding, communication, everyday activities, play, and shared experiences in the local community. The other group receive the standard of care in Uganda.

What are the possible benefits and risks of participating?
All participants will receive at least standard of care, including referral to local services for seizure management and physiotherapy where available. Participants in the intervention arm may benefit from participation in the group training sessions. Participants in the control arm will

receive the intervention programme, adapted for older children, at completion of this study. Since the intervention involves participatory training, there are few anticipated risks of participation, although participants will suffer the inconvenience of visits and interviews, and travel to the study site (transport costs will be refunded).

Where is the study run from?
The host institution for the study will be the Medical Research Council/Uganda Virus Research Institute Research Unit (MRC/UVRI), Entebbe, Uganda. The study will be conducted in two sites: Mulago Hospital and Kiwoko Hospital, Uganda. In Kiwoko, the project implementation partner will be Adara Development, an international development agency that has worked in partnership with Kiwoko Hospital and the surrounding community since 1998.

When is the study starting and how long is it expected to run for?
October 2017 to September 2019

Who is funding the study?
Saving Brains Grand Challenges Canada (Canada)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1

Study information

Scientific Title
The ABAaNA early intervention pilot trial: a randomised feasibility trial of a facilitated, community-based participatory early intervention for young infants at high risk of neurodevelopmental delay and disability in Uganda

Study objectives
A facilitated, participatory, early intervention programme for children at high-risk of neurodevelopmental impairment and disability and their caregivers in Uganda is feasible, acceptable and effective in improving child functioning, nutritional status and quality of life when compared to standard care.

Study objectives:
1. Describe the feasibility and acceptability of the ABAaNA EIP as an intervention for high-risk infants in Uganda with neurodevelopmental delay and impairment
2. Obtain preliminary data on whether the ABAaNA EIP improves functioning, nutritional status and quality of life of high-risk infants and their carers when compared with standard care
3. Identify the main barriers and facilitating factors for scaling up of the programme

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Uganda Virus Research Institute, 27/04/2017, ref: GC/127/17/04/596
2. Uganda National Council for Science and Technology, 29/05/2017, ref: HS2244
3. Mulago Hospital, 07/08/2017, ref: MREC 1205
4. London School of Hygiene & Tropical Medicine, 14/08/2017, ref: 14304

Study design
Two-centre single blind randomised controlled trial with two parallel arms

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neurodevelopmental impairment and disability

Interventions
Children and their caregivers are randomised in a 1:1 ratio to receive either the ABAaNA early intervention programme or standard of care.

Intervention group:
The ABAaNA early intervention programme consists of a 10-modular parent training course delivered over a six-month period and includes two home visits to ensure translation of the skills and learning to the home environment. The program has previously been developed and piloted in Ugandan children using a pre and post-test observational design. Participatory group sessions with 6-10 families (mothers or (and) fathers)/other care-givers are conducted by trained facilitators, themselves parents of children with neurodisability. The content of the training includes positioning, feeding, communication, everyday activities, play, and shared experiences in the local community with a focus on empowering caregivers and the wider family, and an emphasis on peer support and learning. Facilitators receive comprehensive training from existing in-country master trainers established during the pilot study. Individual module sessions will be given every 3-4 weeks and, based on the pilot work, will last 2-3 hours including time for facilitated discussion.

Control group:
Participants in the control group receive the standard level of care.

The early intervention group receive a package involving 10 group training sessions for caregivers delivered over a six-month period (during which time control and case group participants will receive standard of care). Outcomes are assessed at the end of this six-month period (“programme completion”). All participants are then followed for a further six months, and outcomes assessed again at the end of this period (“six months post-programme completion”, 12 months follow-up in total).

Intervention Type
Mixed

Primary outcome measure
1. Feasibility of participant recruitment and randomisation as assessed by the total number recruited and randomised to each arm at baseline. Qualitative tools including focus group discussions and in-depth interviews conducted at baseline, programme completion and at six months post-programme completion will also be used to capture information on feasibility
2. Acceptability of the early intervention programme amongst caregivers and health care workers as assessed by the protocol violation rate (protocol violations may result from

participants in the intervention arm being treated as if they were in the control arm or vice versa) at programme completion. Qualitative tools including focus group discussions and in-depth interviews conducted at baseline, programme completion and at six months post-programme completion will also be used to capture information on acceptability
3. Acceptability of the early intervention programme among caregivers as assessed by number of sessions attended between baseline and programme completion
4. Quality of life as assessed using the scored, validated Pediatric Quality of Life, Family Impact module at baseline, programme completion and at six months post-programme completion

Secondary outcome measures
1. Child functioning as assessed by the Pediatric Evaluation Disability Inventory (PEDI) at baseline, programme completion and at six months post-programme completion
2. Cognitive function as measured using the Griffiths Mental Developmental Scales at baseline, programme completion and at six months post-programme completion
3. Growth and nutrition as measured using weight-for-age, height-for-age, weight-for-height, MUAC and head circumference at baseline, programme completion and at six months post-programme completion
4. Caregiver psychological distress assessed using the Self-Referral Questionnaire (SRQ) and the Parent Stress index (PSI) at baseline, programme completion and at six months post-programme completion
5. Caregiver child attachment is assessed using the Emotional Availability Scales (EAS) for observed emotional availability and the Maternal Responsiveness Instrument (MIR) for self-reported emotional availability at baseline, programme completion and at six months post-programme completion
6. Illness episodes and infant mortality is assessed using questionnaires delivered to the caregiver at baseline, programme completion and at six months post-programme completion
7. The quality of the home environment assessed using the Home Observation for the Measurement of the Environment (HOME) at baseline, programme completion and at six months post-programme completion

Overall study start date
01/10/2017

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Infants and their caregivers must satisfy the following inclusion criteria:
1. Infant aged 6-9 months
2. Infant has moderate-severe developmental impairment defined as a Developmental Quotient (DQ) on the Griffiths Mental Developmental Scales of <70 and/or HINE score <60
3. Informed written consent is provided by caregiver

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
126

Total final enrolment
126

Key exclusion criteria
1. Condition requiring inpatient treatment
2. Caregivers not willing or unable to attend the full programme
3. Main residence outside Nakaseke district or >20km from Mulago Hospital
4. No caregiver informed written consent
5. Accompanying parent or guardian does not speak or understand Luganda or English

Date of first enrolment
08/01/2018

Date of final enrolment
15/10/2018

Locations

Countries of recruitment
Uganda

Study participating centre
Mulago Hospital
Makerere Hill Road
Kampala
Uganda
-

Study participating centre
Kiwoko Hospital
PO Box 149
Luwero
Uganda
-

Sponsor information

Organisation
MRC/UVRI Uganda Research Unit on AIDS

Sponsor details
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NA

Sponsor type
Research organisation

ROR
https://ror.org/04509n826

Funder(s)

Funder type
Government

Funder Name
Saving Brains Grand Challenges Canada

Results and Publications

Publication and dissemination plan
A protocol paper is planned (intention to publish date: 30/04/2018). Trial findings will be submitted for publication in high-impact peer reviewed journals (intention to publish date: 20/09/2020). We plan to disseminate our findings at relevant international conferences. The protocol paper and statistical analysis plan will be added to the registration record once they are finalised.

Intention to publish date
20/09/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/10/2019	14/10/2019	Yes	No
Statistical Analysis Plan	version 2	25/06/2019	16/08/2022	No	No

Results article	13/09/2022	03/10/2022	Yes	No