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Evaluating a programme of early assessment, care and support for children at risk of developmental disabilities and their caregivers in Rwanda: the PDC/Baby Ubuntu trial

Submission date
03/07/2024

Recruitment status
No longer recruiting

Registration date
24/07/2024

Overall study status
Ongoing

Last Edited
25/09/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Globally, 53 million children under 5 years of age around the world are living with a developmental disability. Early child development (ECD) programmes often exclude children with developmental disability, and few studies have examined the health, social, emotional and financial impacts, cost-effectiveness and strategies for sustainability at scale. A sustained and coordinated approach to early detection and intervention is needed to improve the life chances of millions of affected children and their families around the world, particularly those living in the hardest-to-reach communities in the lowest resource settings.
This study will evaluate the PDC/Baby Ubuntu programme, implemented by Partners in Health in Rwanda. The Pediatric Development Clinic (PDC) provides early care for young children at risk of developmental disability, monitoring development and growth, whilst providing support to caregivers. Baby Ubuntu is a structured programme for children with a developmental disability and their caregivers, provided over 11 sessions by a health professional and trained caregiver.

Who can participate?
Children aged 0-5 years and their caregivers in Burera, Kamonyi and Gakenke districts who meet the criteria for being at risk of developmental disabilities

What does the study involve?
The study will assess the impact of the programme on child, caregiver and family outcomes, including participation of children in family and community life and family quality of life. The trial will compare outcomes between participants who attend clinics that are running the programme (intervention group) and those who attend clinics that do not (control group). At the start of the study, the researchers will conduct a baseline survey among participating families. Once this is complete, half of the clinics in the study area will be randomly assigned to the intervention arm and will run the programme. Endline assessment will be conducted 12 months after recruitment and randomisation. After this, the programme will be implemented across all health facilities. Complementary qualitative research will be conducted to assess feasibility and acceptability.

Semi-structured in-depth interviews will be conducted with 25-40 caregivers of children recruited to the trial to explore their experience with and opinions of the PDC/Baby Ubuntu programme. Additionally, 15-25 programme implementers and other key informants will be interviewed about their experience of designing and delivering the PDC/Baby Ubuntu programme.
Feasibility and acceptability will further be assessed by measuring participant programme attendance records. The fidelity of programme delivery will also be assessed. Economic evaluation will be conducted to determine the costs of setting up the programme, the cost-effectiveness of the programme and the main cost drivers.

What are the possible benefits and risks of participating?
No specific discomfort, distress or hazards are expected as a result of any component of the research (participating in surveys and in-depth interviews). Interviews will last about 1 hour per visit and participants will be given the opportunity to stop at any time. Participants will receive remuneration for their time participating in the data collection.
The researchers will monitor serious adverse events throughout the study and whether they are associated with the programme. Standard operating procedures will be in place to action serious adverse events.

Where is the study run from?
The study is run by the London School of Hygiene & Tropical Medicine, Partners in Health and Lifetime Consulting (UK)

When is the study starting and how long is it expected to run?
July 2023 to June 2026

Who is funding the study?
1. Saving Brains, Grand Challenges Canada (TTS-2308-60382)
2. United Kingdom Foreign, Commonwealth and Development Office under the Programme for Evidence to Inform Disability Action (PENDA) (IATI Identifier: GB-EDU-133903-PENDA)

Who is the main contact?
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Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Impact evaluation of the Pediatric Development Clinic/Baby Ubuntu programme of early assessment, care and support for children at risk of developmental disabilities in Rwanda: a cluster randomised-controlled trial, economic evaluation and process evaluation

Study objectives
1. The primary effectiveness hypothesis is that the PDC/Baby Ubuntu programme of early identification, support and care for children at risk of developmental delay and disability integrated within Rwandan government health systems, is effective in improving child participation and family impact quality of life, when compared to care as usual.
2. The primary implementation hypothesis is that the integrated programme is feasible, acceptable and results in high-fidelity adoption of the programme at district level, promoting reach and coverage of tier one services for children with developmental disabilities and their families.

Ethics approval required
Ethics approval required

Ethics approval(s)

1. approved 26/10/2023, London School of Hygiene & Tropical Medicine Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 28527

2. approved 05/12/2023, Rwanda National Research Ethics Committee (Ministry of Health, Kigali, PO Box 84, Rwanda; +250 (0)788 592 004; info@rnecrwanda.org), ref: RNEC213/2023

3. approved 03/05/2024, London School of Hygiene & Tropical Medicine Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 28527 - 01

4. approved 28/02/2024, Rwanda National Research Ethics Committee (Ministry of Health, Kigali, PO Box 84, Rwanda; +250 (0)788 592 004; info@rnecrwanda.org), ref: No.28/RNEC/2024

Study design
Single-blind effectiveness implementation-hybrid (type II) cluster randomized trial (cRCT)

Primary study design
Interventional

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Children with or at risk of developmental disabilities

Interventions
After the baseline survey is complete, clusters will be randomised to the intervention or control arm using a 1:1 allocation ratio. Randomisation will be stratified by district. Depending on the heterogeneity of clusters, a restricted randomisation approach may be required to ensure balance on important characteristics such as cluster size, urban/rural area, and density of available health resources that may be prognostic of intervention outcomes. If restricted randomisation is required to ensure balance, characteristics included in the restriction will be adjusted for in the analysis.

The intervention group will receive the PDC/Baby Ubuntu programme, implemented by Partners in Health in Rwanda. The Pediatric Development Clinic (PDC) provides early care for young children at risk of developmental disabilities, monitoring development and growth, whilst providing support to caregivers. Enrolled children in PDC and their caregivers will be systematically provided with a package of PDC services including health, nutrition and developmental care, following standard visit appointments. Children attending the PDC, identified as having developmental disability are referred to the Baby Ubuntu programme. Baby Ubuntu is a structured programme for children with developmental disabilities and their caregivers, provided over 11 sessions by a health professional and trained caregiver. Each group session lasts for 2-3 hours and is delivered every 2-3 weeks, with the entire programme usually being delivered over six months, including up to three home visits by the facilitators.

All participants in the study, across both the intervention and control arm, will receive information on which services are available to them. This information will be provided in the form of printed handouts, with available services, facility addresses, and contact details listed. This information is provided as enhanced usual care. In the comparison arm, children will receive

enhanced usual care alone for the first 12 months. The PDC/Baby Ubuntu programme will then be implemented in the comparison arm.

Intervention Type
Behavioural

Primary outcome(s)
Co-primary effectiveness outcome measures:
1. Child participation measured using the Young Children's Participation and Environment Measure at baseline and endline
2. Family impact quality of life measured using the Pediatric Quality of Life, Family Impact Module at baseline and endline

Key secondary outcome(s))
Secondary effectiveness outcome measures:
1. Child mortality measured using Severe Adverse Event forms, Electronic Health Records, Caregiver report at baseline and endline
2. Childhood illnesses, such as pneumonia and seizures, measured by parental report and electronic health records at baseline and endline
3. Child development (children without disability) or function (children with disability) measured using the Malawi Developmental Assessment Tool, the Global Scales of Early Development or the Pediatric Evaluation of Disability Inventory Computer Adaptive Test at baseline and endline
4. Child growth and nutritional status measured using weight-for-age, height-for-age, weight-for-height malnutrition at baseline and endline
5. Caregiver skills in caring for a child with developmental disability measured using pre- and post-Parent Skills Training Test for Caregivers at baseline and endline
6. Caregiver mental health measured using self-report questionnaire at baseline and endline
7. Caregiver experiences of stigma measured using the Affiliate Stigma Scale at baseline and endline
8. Caregiver livelihood and economic activity measured using Time-use survey from Living Standards Measurement Survey at baseline and endline

Other exploratory outcome measures:
1. Child supervision and child discipline measured using the relevant module from the UNICEF-supported Multiple Indicator Cluster Survey (MICS) at baseline and endline
2. Family support for their child's need and experience of early intervention will be measured using the Family Outcomes Survey (Revised) at baseline and endline
3. Access to disability-related goods and services will be measured using caregiver report at baseline and endline

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Eligible participants will be children at risk of developmental disability aged 0-5 years, and their caregivers where 'at risk' is defined as:
1. History of a newborn condition that is a recognised risk factor for developmental disability: prematurity, neonatal infection, neonatal encephalopathy ('birth asphyxia'), severe jaundice, cerebral malaria, suspected genetic and chromosomal conditions, and seizures.

2. Not meeting age-specific developmental milestones as identified through routine child health services
3. Positive screening for developmental disability assessment on caregiver report

Inclusion criteria:
1. Children (0-59 months) meeting the definition of ‘at risk’ and their caregivers as above
2. Living within the catchment area of one of the health centres in a study cluster
3. Caregiver willing and able to give written informed consent to take part in the evaluation
4. Caregiver is either 18 years of age or older, or, if the caregiver is younger than 18 years and the biological parent of the child, they are considered emancipated youth and eligible for participation

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 months

Upper age limit
5 years

Sex
All

Key exclusion criteria
Children requiring hospital treatment at the time of the baseline assessment and those in institutional care

Date of first enrolment
01/03/2024

Date of final enrolment
12/07/2024

Locations

Countries of recruitment
Rwanda

Study participating centre
Burera District Office
Rusarabure
Burera District

Rwanda
N/A

Study participating centre
Gakenke District Office
Kigali-Ruhengeri Road
Gakenke District
Rwanda
N/A

Study participating centre
Kamonyi District Office
Kigali-Muhanga Road
Kamonyi District
Rwanda
N/A

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Foreign, Commonwealth and Development Office

Alternative Name(s)
Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: https://datacompass.lshtm.ac.uk/

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.3	25/04/2024	04/07/2024	No	Yes
Participant information sheet	version 2.3	25/04/2024	04/07/2024	No	Yes
Participant information sheet	version 2.4	29/11/2024	01/09/2025	No	Yes
Participant information sheet	version 2.4	29/11/2024	01/09/2025	No	Yes