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The Missing Billion: Addressing healthcare access needs for people with functional difficulties in Luuka district, Uganda

Submission date 18/04/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 24/05/2024	**Overall study status** Ongoing	[X] Statistical analysis plan [_] Results
Last Edited 07/05/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Evidence shows that people with disabilities face barriers to accessing healthcare, which contributes to their poorer average health status and shorter life expectancy. Participatory community approaches have been successful in improving healthcare access for other marginalised groups, but have not yet been trialed for people with disabilities. This study aims to assess whether Participatory Learning and Action for Disability (PLA-D) can reduce mortality and unplanned hospitalization of people with disabilities in Uganda.

Who can participate?
People with disabilities of all ages (or their carers) who live in the selected villages in Luuka District, Uganda

What does the study involve?
This study is a cluster randomised control trial that involves randomly assigning groups (clusters) of participants rather than individuals to different interventions, allowing researchers to assess the effectiveness of treatments or interventions in real-world settings. This study also has integrated process and economic evaluations. The trial will evaluate a community-based four-phase PLA-D cycle intervention focused on improving access to healthcare for people with disabilities (implemented over 12 months) compared to control. Both control and intervention clusters will receive health system strengthening components of healthcare worker training on disability, and health facility accessibility audits.

What are the possible benefits and risks of participating?
We cannot promise the study will help individuals or their households, but the information from the study will help our knowledge and understanding of how to improve the health and quality of life of people with disabilities. Participants will be offered UGX 15,000/= as compensation for completing the questionnaire.

No risks or disadvantages are perceived for participants in taking part, other than the time required to answer all the questions. Participants are free to take a break or ask to stop entirely at any time without providing a reason.

Where is the study run from?
The study is led by the London School of Hygiene and Tropical Medicine in the UK, in partnership with Makerere School of Public Health and MRC/UVRI & LSHTM Uganda Research Unit. PLA-D group implementation is being led by AMREF Health Africa.

When is the study starting and how long is it expected to run for?
December 2021 to July 2026

Who is funding the study?
1. The Foreign, Commonwealth & Development Office, FCDO under the Programme for Evidence to Inform Disability Action (PENDA)
2. The National Institute for Health and Care Research (NIHR)

Who is the main contact?
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Contact information

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Public, Scientific

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Study information

Scientific Title
The Missing Billion: Community-based participatory learning and action groups to address healthcare access issues for people with disabilities in Uganda

Acronym
The Missing Billion

Study objectives
Participatory learning and action for people with disabilities (PLA-D) in Uganda will improve the ability of people with disabilities to access healthcare, and consequently improve health, quality of life, attitudes, participation, health expenditure, and ultimately reduce unplanned hospitalization and mortality.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 31/01/2024, London School of Hygiene & Tropical Medicine - Observational /Interventions Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44(0)2076368636; ethics@lshtm.ac.uk), ref: 29927

2. approved 14/06/2022, Uganda Virus Research Institute (Plot 51-59 Nakiwogo Road, Entebbe, -, Uganda; +256414320385; directoruvri@uvri.go.ug), ref: GC/127/904

3. approved 10/08/2022, Uganda National Council for Science and Technology (Plot 6 Kimera Road, Ntinda, Kampala, -, Uganda; +256414705500; info@uncst.go.ug), ref: SS1348ES

Study design
Pragmatic cluster-randomized parallel-group two-arm superiority trial with integrated process and economic evaluations

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Participatory learning and action groups for disability

Interventions
The trial will evaluate a community-based four-phase Participatory Learning and Action for Disability (PLA-D) cycle intervention, locally known as “Tusobola” or “We Can”, the intervention is focused on improving access to healthcare for people with disabilities (implemented over 12 months) compared to control. Both control and intervention clusters will receive health system strengthening components of healthcare worker training on disability, and health facility accessibility audits. 100 clusters will be randomly allocated (1:1) to the intervention or control arm. Clusters are villages in Luuka District, Uganda, selected to be geographically distinct. To ensure balance between the arms using restricted randomization based on key criteria, including cluster size, and one of the primary outcomes, unplanned hospitalization. Allocation of the villages to control or intervention arms will be conducted by LSHTM and occur at a one-time point post-baseline, but prior to intervention implementation.
Villages in the intervention arms will establish community groups of approximately 20 people with disabilities. However, the classification of disability to participate in the groups is through self-identification, rather than objective assessment or screening. A further 10-20 carers of people with disabilities/children and/or community members will also be able to join the groups as non-members. The content of the group discussion will be centred around health and access to health for people with disabilities, but specific content and discussion topics will be brought up by group members. The groups will meet in person and will be governed internally by a committee of members, including a chair, vice-chair, secretary, vice-secretary, and treasurer to oversee the organisation of the group. The group meetings will be led by a facilitator and co-facilitator, selected from the groups by the members and who are ideally either disabled themselves, or carers/relatives of people with disabilities. Each sub-county will also have group managers (a Community Development Officer who oversees 2 group supervisors) and group supervisors (Health Assistants or Parish Chiefs who oversee 4 to 5 groups). The facilitators, supervisors and managers will attend a week-long training workshop. During the training, they will learn about health, disability, the use of participatory facilitation techniques, the PLA-D cycle, and how to conduct and manage group meetings (e.g. safeguarding, managing expectations, progress recording and reporting). Facilitators will be provided with a facilitator manual and will be supported by a supervisor (one supervisor per three facilitators). There will be monthly monitoring of facilitators by supervisors.

Facilitators will lead groups through a cycle of regular monthly meetings to help them collectively identify key problems about health /healthcare access facing people with disabilities. Facilitators will use discussion prompts, picture cards and other accessible tools to stimulate discussion. The groups will develop an action plan to deliver group-identified solutions and share progress to engage the wider community to support action. The groups will be convened for at least one year.

For the health system strengthening interventions that will be implemented across control and intervention arms, all 42 health facilities across the 12 sub-counties in Luuka district will be included – irrespective of ownership (public or private not-for-profit) or health facility level (clinic, HC II, HC III, HC IV). For each health facility, 2-4 healthcare workers (irrespective of cadre type) will be invited to participate in the disability training. Training will be delivered twice in each sub-county (24 trainings in total), so each health facility has two opportunities for their healthcare workers to attend. Each training will be delivered by a pair of trainers – one trainer with a disability and another trainer who is a healthcare worker. There are 10 trainers in total, five who are people with disabilities and five who are healthcare workers. They were purposively

selected as they worked/lived in the area, and they went through piloting of the training intervention in September and October 2023. The trainers undertook a two-day training of trainers through the pilot, during which participants received a trainer manual. The training of trainers covered effective training and learning approaches, the content of the disability training, and incorporated practical sessions – including practice delivering the course. All trainers will be offered refresher training prior to the roll-out of the health worker training in 2024. The disability training will then be delivered by the trainers to groups of 12-14 healthcare workers in one day. The training will cover understanding disability; motivations for becoming a health professional (and how this relates to disability-inclusive healthcare); disability and equitable healthcare; interacting and communicating with people with disabilities; referring persons with disabilities; and auditing health facilities for accessibility. Further to the training, all attendees will receive a participant manual.

For the health facility audits, an accessibility checklist, adapted from the Disability Awareness Checklist (DAC) and pilot tested in October 2023, includes 50 core items across the thematic areas of Universal Design and Accessibility, Reasonable Accommodation, Capacity of staff and Linkages to other services. Up to 20 additional items are collected specifying further detail on core items, depending on the responses to core items reported (e.g. additional questions on accessible toilet wash points, if accessible toilets are reported). The Universal Design and Accessibility section includes measurements of various facility infrastructure heights and widths (e.g. entranceway width, height of reception desk) and the slope of any access ramps, requiring a standard tape measure and angle measure (Angle Meter Pro Android App as recommended by the DAC tool developers) respectively. All length measurements are taken in a straight line (180°) at the narrowest point of the infrastructure under investigation as this is the useable length for the patient. For long ramps (over 2m), 2-3 measurements are taken at various points along the length the steepest (highest number) is recorded. In addition, the GPS locations are recorded for the locations of a) the facility b) the nearest public transport drop off (boda stage) c) the nearest private taxi drop off. Two facilitators with disabilities will be recruited and trained to complete the accessibility checklist using materials developed during the pilot. The training will include guidance on preparing for and completing the DAC, processes and logistics, and practice at a nearby health facility. The practical session will allow the facilitators to practice taking measurements and familiarise themselves with the tool. Facilitators will work together with the healthcare worker disability trainers to attend the first round of the healthcare worker disability training sessions and lead a short (30-minute) introduction to the accessibility audit tool for attendees. They will then liaise with the attendees to visit their healthcare facilities (n=42 across all 12 sub-counties). Audit data will be collected using a purpose-designed REDCap form on an encrypted Android device. In addition, a facility feedback form developed for the pilot will be used to record key findings and facility personnel responses on any potential areas for change.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome(s) as of 07/05/2026:

Mortality or unplanned hospitalisation among people among people with disabilities in the study clusters measured using reports from household members (mortality) or participants (hospitalisation) and verified through two sources (e.g., family and neighbour/death certificate (mortality)/ participant's hospital book (hospitalisation) during 24 months of follow-up

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Previous primary outcome(s):

Mortality and unplanned hospitalization among people with disabilities in the study clusters measured using reports from household members (mortality) or participants (hospitalisation) and verified through two sources (e.g., family and neighbour/death certificate (mortality)/ participant's hospital book (hospitalisation) during 24 months of follow-up

Key secondary outcome(s))

Current key secondary outcome(s) as of 07/05/2026:

The following secondary outcome measures will be assessed at baseline and endline (24 months post-baseline):
1. Quality of life measured using WHO-QOL BREF for adults 18+ years and PedsQL Parent Report for children 2-18 years
2. Health expenditure measured through participant self-report of healthcare costs. Total outpatient costs in Ugandan shillings (UGS) will be reported for individuals who had an outpatient visit to a health facility in the last 3 months. Total inpatient costs will be reported for individuals who had a visit that included an overnight stay in the last 3 months. Transport costs will be reported for outpatient and inpatient visits.
3. Morbidity measured using a questionnaire adapted from the WHO Model Disability Survey, which assesses the presence and severity of 23 health conditions. We will analyse the presence /absence of each condition as well as the total number of conditions.
4. Attitudes measured using the Model disability survey question set for adults 18+ years on attitudes towards disability, which assesses both personal and perceived societal attitudes.
5. Participation measured using SINTEF participation questionnaire for adults 18+ years and CASP question set for children 5-18 years.
6. Health access measured using the following variables related to access to health care which will be analysed separately : 1) In the last 3 months did you need health care? 2) Where did you go most often when you felt sick or needed to consult someone about your health? 3) What was the main reason you needed care, even if you did not get care? 4) Which reason(s) best explains why you did not get health care?
7. Health care quality/satisfaction: This outcome will be assessed at baseline and endline using four questions capturing different aspects of quality with each item scored on a 5-point scale and an overall quality score will be calculated.

Intervention implementation costs are measured using implementation cost data at endline.

Additionally, Mortality and unplanned hospitalisation will be reported separately as secondary outcomes well as combined in the primary outcome.

Verbal autopsy data will be available for all reported deaths in the 6 months before endline.

Data on unplanned hospitalisations will be available for at least 10% of events in the six months preceding the endline, collected using a verbal autopsy type approach.

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Previous key secondary outcome(s):

The following secondary outcome mesaures will be assessed at baseline and endline (24 months post-baseline):
1. Quality of life measured using WHO-QOL BREF for adults 18+ years and PedsQL Parent Report for children 2-18 years
2. Health expenditure measured through participant self-report of healthcare costs incurred over the past 6 months, including direct costs (e.g., consultation fees, medication costs) and indirect costs (e.g., transportation costs)
3. Morbidity measured using a questionnaire adapted from the WHO Model Disability Survey
4. Attitudes measured using the Model disability survey question set for adults 18+ years
5. Participation measured using SINTEF participation questionnaire for adults 18+ years and CASP question set for children 5-18 years
6. Health access measured using a composite score derived from principal components analysis of items assessing coverage, quality, affordability, and barriers to healthcare access

Intervention implementation costs are measured using implementation cost data at endline

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Reside in a cluster village
2. Have a disability
3. Provide consent (themselves or via their caregiver/head of household) for involvement in the trial

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
0

Key exclusion criteria
Living outside the cluster village

Date of first enrolment
06/09/2024

Date of final enrolment
06/09/2024

Locations

Countries of recruitment
Uganda

Study participating centre
Amref Health Africa in Uganda
Plot 01 Okurut Road Kololo
P.O. Box 10063
Kampala
Uganda
-

Study participating centre
Makerere University
7062 University Rd
Kampala
Uganda
-

Study participating centre
MRC/UVRI & LSHTM Uganda Research Unit
Plot 51 – 59 Nakiwogo road
P.O. Box 49
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-

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 (FCDO)

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
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 anonymised quantitative datasets from the baseline and endline surveys will be stored in a publicly available repository, specifically LSHTM's Data Compass (datacompass.lshtm.ac.uk), 12 months after the end of the trial. Explicit consent has been included for making data open access. Qualitative data will not be made available as it may be possible to infer who the respondent is even after anonymization.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		29/04/2024	31/07/2024	No	No
Statistical Analysis Plan	version 4.1	21/04/2026	07/05/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes