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Asthma care for children and adolescents in Uganda

Submission date 14/05/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 25/05/2024	**Overall study status** Ongoing	
Last Edited 07/07/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

Asthma is the most common long-term disease in children across the world but mainly affects those in low-income countries like Uganda. They suffer from severe and frequent asthma symptoms and attacks, and this leads to very frequent emergency clinic visits and hospital admissions. A lot of the scarce financial resources are spent on these visits, children miss school, and their caregivers miss work, worsening the poverty for the affected families. The affected children and their caregivers experience psychosocial challenges including stigma, which contributes to the overall poor quality of life of the affected persons and their families. The uncontrolled asthma symptoms also increase the risk of developing other long-term diseases like chronic obstructive pulmonary disease.

Many children and adolescents in Uganda have asthma. However, recent studies conducted in Uganda indicated that many children with asthma do not know because they have not yet been told by health workers that they have asthma. For this reason, they do not get the right treatment. This affects their health and well-being, and other activities including play and school. Untreated asthma also affects their growth and development. In addition, parents and guardians spend a lot of money on trying to treat their children, but because the diagnosis of asthma is not yet known, the money is spent on other medicines like cough syrups that do not help. It is therefore important that people with asthma are identified early and given the correct treatment and care to minimize the physical, economic and psychosocial problems associated with asthma.

In this study, we would like to find out whether checking for symptoms of asthma in every child or adolescent who visits the health centres with respiratory problems can help to identify those with undiagnosed asthma.

This study aims to understand whether innovations like checking for symptoms of asthma in every child or adolescent who visits the health centres with respiratory problems can help to identify those with undiagnosed asthma. The study will also provide information on whether education about asthma directed to patients and their caregivers can lead to improvements in the understanding of asthma, use of medicines and subsequent reduction in frequency of symptoms.

Who can participate?

Children aged 2 months up to 17 years and their parents/guardians

What does the study involve?
The health facilities in the study site (Jinja district in Southeastern Uganda) will be randomly divided into two groups. In one group, the healthcare workers will be given a standard form to be used to check for asthma symptoms among children and adolescents who will present with symptoms of respiratory diseases such as cough and difficulty breathing. The checking will be done by asking questions about asthma symptoms. A physical examination will also be done. The second group will continue their usual practices of care. Data on the number of children diagnosed with asthma before and during the study will be collected and compared to determine whether the routine checking for asthma symptoms can increase the number of children diagnosed with asthma. A similar approach will be used in another study in which community health workers (also known as Village Health Teams [VHTs] in Uganda) will be oriented about asthma and participate in educating the patients about asthma and asthma care, and how this can lead to better health for the affected children.

What are the possible benefits and risks of participating?
Parents/guardians and their children may benefit from knowing that the child has asthma because of participating in the study. In addition, they will have an opportunity to receive the recommended care which may ultimately improve their health and well-being. In addition, the participants may benefit from increased knowledge and understanding of asthma. There are no risks or discomforts directly arising from participating in the study. The study will involve asking questions about asthma symptoms and a physical examination only. There will be no tests done on the participants.

Where is the study run from?
Makerere University (Uganda)

When is the study starting and how long is it expected to run for?
August 2023 to October 2027

Who is funding the study?
This study is jointly funded by the United Kingdom (UK) Medical Research Council (MRC) and the UK Foreign, Commonwealth & Development Office (FCDO) under the MRC/FCDO Concordat agreement and is carried out in the framework of the Global Health EDCTP3 Joint Undertaking

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MR/X031713/1

Study information

Scientific Title
Improving access to asthma care for children and adolescents in Uganda

Acronym
ACCA

Study objectives
This trial is composed of two sub-studies. The sub-studies are both cluster randomized trials with different study populations and outcomes. The research questions are outlined below.
1. What is the feasibility, acceptability, and effectiveness of routine screening for asthma symptoms among children and adolescents with respiratory illnesses in improving the identification of patients with undiagnosed asthma?
2. What is the feasibility, acceptability, and effectiveness of community health worker-led asthma education in improving asthma outcomes among children and adolescents?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/04/2024, Makerere University School of Public Health Research and Ethics Committee (College of Health Sciences, Upper Mulago Hill Road, Kampala, -, Uganda; +256 (0) 773 785 333; jkagaayi@musph.ac.ug), ref: SPH-2024-552

Study design
Cluster randomized trial

Primary study design
Interventional

Secondary study design

Cluster randomised trial

Study setting(s)
Other

Study type(s)
Diagnostic, Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Asthma

Interventions
The unit of randomization will be health facilities in the study area. The method is simple randomization. The primary care facilities of interest have 2 levels; 5 Health Centre IV (HC IV) and 12 Health Centre III (HC III) based on the range of services provided. 4 HC IVs and 4 HC IIIs will be randomly selected to participate in the study. The 4 HC IVs will be randomly allocated to the intervention and control groups in a ratio of 1:1. The same process will be followed for HC IIIs. The total number of study sites will be 8 (4 intervention and 4 control). It is a single-centre study.

The intervention for the first research question (What is the feasibility, acceptability, and effectiveness of routine screening for asthma symptoms among children and adolescents with respiratory illnesses in improving identification of patients with undiagnosed asthma?) is routine screening for asthma symptoms among all children with respiratory symptoms attending the intervention facilities for clinical care. A standard screening tool will be used. In the control arm, children and adolescents with respiratory symptoms will be assessed as usual and no screening tool will be used.

To assess if routine screening for asthma symptoms can identify children with undiagnosed asthma, the researchers shall collect baseline data on asthma diagnoses in both the control and intervention health facilities. The baseline data will be asthma diagnoses in the 12 months prior to starting the intervention. The researchers shall also prospectively collect data on asthma diagnoses per month during the study period. They shall then compare the asthma diagnoses between the control and intervention facilities to estimate the difference in asthma diagnoses attributable to routine screening. They shall use a random-effects logistic regression model to adjust for baseline data while accounting for facility-level clustering. Intention-to-treat analysis will be used.

The intervention for the second research question (What is the feasibility, acceptability, and effectiveness of community health worker-led asthma education in improving asthma outcomes among children and adolescents?) is asthma education delivered by Community Health Workers (also known as Village Health Teams [VHTs] in Uganda). Participants in the intervention health facilities will be given asthma education by VHTs after consultation with the clinicians. A standardized package of messages will be provided to them. The participants in the control health facilities will receive standard care as provided by the clinicians and no asthma education by VHTs. The participants in both arms will be followed up at months 1, 3 and 6. At each of these visits, asthma education will be provided by VHTs (for the intervention arm) and asthma control scores will be assessed in both arms.

To assess if asthma education delivered by VHTs can help to achieve asthma control for children and adolescents with asthma, the researchers shall collect baseline data on asthma control for all participants in both the control and intervention health facilities. They shall also prospectively collect data on asthma control scores at months 1, 3 and 6. The asthma control scores will be determined using age-appropriate asthma control tools. To estimate the mean difference in asthma control scores between the intervention and control arms, adjusted for baseline scores and facility-level clustering, the researchers shall use a random-effects linear regression model and intention-to-treat analysis.

Intervention Type
Other

Primary outcome measure
The primary outcome for the 1st CRT on routine screening for asthma symptoms is the proportion of asthma diagnoses measured using a questionnaire at the time of enrolment into the study (this trial has only one visit - no follow-up visits)

The primary outcome for the 2nd CRT on asthma education delivered by VHTs is asthma control measured using age-appropriate asthma controls tool at baseline, 1, 3 and 6 months

Secondary outcome measures
The secondary outcome measures for the 1st CRT on routine screening for asthma symptoms are:
1. Symptom severity measured by questionnaire at enrolment
2. Asthma control scores measured by asthma control test at enrolment

The secondary outcome measures for the 2nd CRT on asthma education delivered by VHTs are:
1. Emergency care visits due to asthma symptoms measured by questionnaire at month 6
2. Missed workdays by parents/guardians due to asthma in their child measured using a questionnaire at baseline, 1,3 and 6 months
3. Missed school days (where applicable) due to asthma measured using a questionnaire at baseline, 1,3 and 6 months
4. Hospitalizations due to asthma measured by questionnaire at month 6

Overall study start date
01/08/2023

Completion date
31/10/2027

Eligibility

Key inclusion criteria
1. Children aged 2 months up to 17 years
2. Respiratory symptoms at the time of attending the study health facilities
3. Diagnosis of asthma at enrolment (for CRT on asthma education)
4. Ability to attend follow-up visits at months 1, 3 and 6 (for the CRT on asthma education)

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Months

Upper age limit
17 Years

Sex
Both

Target number of participants
CRT on routine screening: 2100 and CRT on asthma education: 300

Key exclusion criteria
1. Children attending the health study health facilities for other services including disease prevention and health promotion services like immunization, growth monitoring and reproductive health
2. Children who will be unaccompanied and without any contact information for reaching their parents/guardians
3. Patients who will present after 5:00 p.m. and in the night will be excluded due to the difficulties of having the research team on site during this time

Date of first enrolment
30/07/2024

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
Uganda

Study participating centre
Makerere University Lung Institute
College of Health Sciences
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Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Results and Publications

Publication and dissemination plan
The protocol manuscript is still under development and will be submitted to peer-reviewed journals.

The results from this study will be published in peer-reviewed journals. They will also be presented at scientific conferences. Feedback meetings with the study sites will be organized to share key findings. The results will also be disseminated to key national stakeholders including the Ministry of Health through meetings and policy briefs

Intention to publish date
01/08/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be made available upon request from Rebecca Nantanda (rnantanda@gmail.com, rebecca.nantanda@mli.mak.ac.ug).
The type of data that will be shared: details not available yet, to be added later.
Dates of availability: dates not available yet, to be added later.
Whether consent from participants was required and obtained: Consent for future use of anonymized data is not required except in cases where samples/body tissues are obtained. This study does not involve any collection of samples.
Comments on data anonymization: Participant data is anonymized at collection. The data does not contain identifiers such as name and telephone contacts. Only study IDs are assigned at the time of enrolment.
Any ethical or legal restrictions: The data can only be used for non-profit educational or research purposes or other non-commercial use.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/07/2025	07/07/2025	Yes	No