A proposal to improve the prevention, identification and treatment of children with malnutrition through the implementation of family-led MUAC program and its assessment in the West Nile region of Uganda

Submission date	Recruitment status	Prospectively registered
23/08/2022	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
08/09/2022	Completed	Results
Last Edited	Condition category	[] Individual participant data
05/09/2022	Nutritional, Metabolic, Endocrine	Record updated in last year

Plain English summary of protocol

Background and study aims

In Uganda, about 8 million children in a year become wasted or develop acute malnutrition and only 10 – 15% access treatment despite decentralized close outpatient (OTC) and inpatient (ITC) treatment care services. Among the contributing factors to this access gap is the weak community health system approach in the country for population engagement to be knowledgeable with presence of children having child wasting and this has affecting early identification and referral of involved children. Therefore, the Ministry of Health (MOH) together with UNICEF and other national partners, revised the national guidelines for integrated management of acute malnutrition (IMAM) using facts from research that trained caregivers can exactly identify a child with wasting using color-coded mid-upper-arm circumference (MUAC) measuring tape and checking for presence or absence of pitting swelling of both feet. The approach in IMAM guidelines for training family caregivers inclusive of mothers, fathers and other family members to screen their children for malnutrition using MUAC was named "Family Led MUAC Program" and planned to start in six host refugee districts of the West Nile region in Uganda.

The objective for Family MUAC Program roll-out in select districts was to assess the barriers and facilitators for the program implementation; uptake and acceptance by caregivers and health providers at health facilities and community settings to increase identification and referral of children with malnutrition to healthcare services.

Who can participate?

Healthcare workers in all health facilities in districts of Arua City, Arua district, Koboko, Madi Okollo, Terego and Yumbe and all community health workers referred to as village health teams (VHTs) in each district will be to trained to routinely train family caregivers in procedures for Family MUAC Program during healthcare visits at the facility or during community outreaches.

What does the study involve? (for participants)

The study will assess the program before, during and after implementation to understand the factors affecting implementation, process and expected results. The healthcare workers, community VHTs, and family caregivers will be interviewed and observations will be made to understand program reach to beneficiaries, appropriateness, acceptability, feasibility, beneficiary ability to do and change to program needs or standards, involved costs, and program sustainability.

What are the possible benefits and risks of participating?

Program roll-out, implementation and planned assessments will enable the MOH and partners understand or gain situational experiences, lessons and best practices to guide national program implementation scale-up and program reporting system. The healthcare providers and community VHTs will attain refresher skills in service delivery, family caregivers and involved children will have increased awareness, access and being in-charge of their health and nutrition status. Minimal risks are likely such as fatigue during interview sessions or workload to health providers.

Where is the study run from?

The program implementation will be conducted by the local district, health facility and community systems and involved teams. The School of Medicine College of Health Sciences at Makerere University (Uganda) will conduct the assessments and provision of technical assistance in program implementation or delivery.

When is the study starting and how long is it expected to run for?

Who is funding the study?

The program implementation and assessments are funded by UNICEF Uganda and the government of Uganda through the Ministry of Health and local district governments in the involved districts. UNICEF Uganda provided funds for field program implementation and its assessments and the government provided the healthcare system, infrastructure and the involved human resource.

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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

Enhance integrated management of acute malnutrition with family-led MUAC implementation science research in the West Nile region of Uganda using a single quasi-experimental design: FMUAC

Acronym

FAMUAC

Study objectives

Family Led MUAC Program improves community prevention, detection and referral of children with wasting in a health care system

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Approved 30/09/2021, Primary IRB Makerere University School of Biomedical Sciences Research and Ethics Committee (SBSREC, Upper Mulago Hill Road Kampala, Uganda; +256-752-575050; erisamwaka@gmail.com), ref: SBS-2021-59
- 2. Approved 01/12/2021, Uganda National Council for Science and Technology (UNCST, Plot 6 Kimera Rd, Kampala P.O. BOX 6884, KAMPALA, Uganda; no telephone number provided; no email provided), ref: UNCST HS1828ES

Study design

Quasi experimental design with pre- and post- Family Led MUAC program implementation research evaluations

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Child wasting

Interventions

A single Quasi experimental design with pre-program and post-program intervention evaluations in involved districts to assess the clinical/program effectiveness and implementation outcomes will be employed because of ethical, practical and funding considerations.

The program interventions and in line with the Ministry of Health guidelines for management of acute malnutrition will aim to

- 1) strengthen organization of districts, training and mentorship of district health teams, health facility staff and community workforce in implementation of Family Led MUAC for improved access and service coverage of nutrition interventions in each district,
- 2) improve prevention, screening for early detection, treatment and follow-up of children with acute malnutrition,
- 3) improve quality of care standards for improved outcomes nutrition patient outcomes.

Health workers at the district, health facility and community level systems will be purposively selected and interviewed every three months for one year. A random sample of 19 family caregivers with children less than five years within the health facility catchment area will be selected and interviewed once in the last quarter of the program implementation.

Intervention Type

Other

Primary outcome(s)

Reach to beneficiaries, appropriateness, acceptability, feasibility, adoption, fidelity, involved costs, and program sustainability will be assessed using interviews every 3 months for 1 year

Key secondary outcome(s))

- 1. Proportion of children screened at community level measured using mid-upper-arm circumference measuring tape every 3 months for 1 year
- 2. Establishment of barriers and facilitators of program implementation assessed using interviews every 3 months for 1 year

Completion date

01/12/2022

Eligibility

Key inclusion criteria

Family caregivers with children under five years of age and have been residents for three months or more

Health providers at the district, health facility and community levels.

Participant type(s)

All

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Family caregivers with neurological impairment and unable to respond coherently in an interview

Date of first enrolment

01/12/2021

Date of final enrolment

01/12/2021

Locations

Countries of recruitment

Uganda

Study participating centre Makerere University

Department of Paediatrics and Child Health School of Medicine College of Health Sciences Upper Mulago Hill Road Kampala Uganda 7072

Sponsor information

Organisation

Makerere University

ROR

https://ror.org/03dmz0111

Funder(s)

Funder type

Charity

Funder Name

UNICEF Uganda

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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?

Participant information sheet