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Severe acute malnutrition treatment delivered by community health workers in emergency settings of Mali (iCCM+ Project)

Submission date
28/09/2020

Recruitment status
No longer recruiting

Registration date
15/10/2020

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Severe acute malnutrition (SAM) is the most extreme and visible form of undernutrition. Children with SAM have very low weight for their height and severe muscle wasting. According to the latest estimates, 16.9 million children under-five worldwide suffer from SAM, making it a major public health concern. Over the past two decades, there have been significant shifts in how the world addresses SAM, changing from inpatient to outpatient treatment due to the development of Ready-to-Use Therapeutic Food (RUTF) and the Community Management of Acute Malnutrition (CMAM) protocol. However, a study in 21 low-and-middle-income countries showed that CMAM programmes reach less than 40% coverage due to critical barriers such as carers' awareness of children's conditions, awareness of programme existence, and high opportunity costs mainly due to distance from health centres.

These challenges are not unique to SAM, and public health services have sought ways of making critical child survival interventions more integrated and more accessible. The Integrated Community Case Management (iCCM) strategy is based on training non-medical Community Health Workers (CHWs) to provide selected curative services for high mortality infectious diseases. Given the influence of nutritional status on the recovery, this protocol also includes the identification and referral of SAM children. Thus, iCCM has been described as a logical platform and missed opportunity to increase the coverage of uncomplicated SAM treatment and prevent malnutrition. Along with this, there is a growing interest in exploring other alternative treatment protocols that will simplify managing the disease by making it easier for non-medical personnel.

Who can participate?
Children 6 to 59 months of age with uncomplicated severe acute malnutrition.

What does the study involve?
A cluster-randomized controlled trial with three arms has been designed to be put in place in the region of Gao in Mali. One arm will be the control by applying the current community program existing in the country. The first intervention arm aims to evaluate the individual effect of

adding the CHWs as treatment providers outside the health facilities (closer to the communities) since they will apply the same protocol as in the control group. The second intervention arm aims to test the effectiveness of simplifying this protocol using the Mid-Upper Arm Circumference (MUAC) as the only diagnostic criterion for admission and discharge and giving a fixed dose of therapeutic food.

What are the possible benefits and risks of participating?
The main benefit is to bring nutritional treatment closer to children in remote or isolated rural villages. It is expected to reduce the dropout possibility and promote adherence to treatment by reducing the family's time and money to bring the child for treatment. Those children treated by the Community Health Workers will also receive nutritional treatment integrated with the most deadly infectious diseases.
The potential risks are that children treated by Community Health Workers may not receive a quality of care as good as that offered by health staff in health centers, which may negatively affect the speed of recovery or on their treatment outcomes.

Where is the study run from?
Health Facilities and Health huts (Community Health Workers) of the Gao Region in Mali, co-ordinated by Action Against Hunger (Action Contre la Faim, ACF), Mali

When is the study starting and how long is it expected to run for?
July 2019 to September 2021

Who is funding the study?
1. Elrha - Enhancing Learning and Research for Humanitarian Assistance (UK)
2. USAID/OFDA - Office of United States Foreign Disaster Assistance (USA)

Who is the main contact?
Noemí López-Ejeda, PhD, noemilop@ucm.es

Study website
https://www.elrha.org/project/effectiveness-cost-effectiveness-and-coverage-of-severe-acute-malnutrition-sam-treatment-delivered-by-community-health-workers-chws-in-mali-and-senegal/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness, cost-effectiveness, and coverage of the treatment of severe acute malnutrition delivered by community health workers through a protocol based on simplified approaches in emergency settings of Mali

Acronym
iCCM+ Project

Study objectives
The decentralization of treatment through Community Health Workers with a modified protocol will increase coverage and cost-effectiveness while maintaining quality standards in the outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/09/2019, Clinical Research Ethics Committee of the Hospital Clínico San Carlos (Comité de Ética de Investigación Clinica del Hospital Clínico San Carlos, Madrid, Spain; +34 91 330 34 13; ceic.hcsc@salud.madrid.org), ref. 19/363-R_X_BC
2. Approved 07/01/2020, National Institute of Public Health (Institut National de Sante Publique, Route de Koulikoro, rue 235, porte 52, BP 1771, Bamako, Hippodrome, Mali; +223 66766337; no email provided), ref. 35/2019/CE-EX-INRSP

Study design
Cluster randomized controlled non-inferiority trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Uncomplicated severe acute malnutrition of children 6 to 59 months

Interventions
The study design includes three arms:

- Control arm: treatment is provided only in health centers following the national protocol.
Admission criteria: Edema +/++ and/or WHZ <-3 z-score and/or MUAC <115mm.
Treatment: RUTF according to weight (170 Kcal/kg/day).
Discharge criteria: WHZ >-1.5 z-score or MUAC >=125 mm.

- Intervention Arm 1: treatment is provided in health centers and outside by community health workers following national protocol.
Admission criteria: Edema +/++ and/or WHZ <-3 zscore and/or MUAC <115mm.
Treatment: RUTF according to weight (170 Kcal/kg/day).
Discharge criteria: WHZ > -1.5 zscore or MUAC >=125 mm.

- Intervention arm 2: treatment is provided in health centers and outside them by community health workers following a modified protocol.
Admission criteria: Edema +/++ and/or MUAC <115mm.
Treatment: fixed amount of 2 sachets of RUTF /day (1000 Kcal/day) except children under 5Kg who will receive 1 sachet/day (500Kcal/day).
Discharge criteria: WHZ >-1.5 z-score or MUAC >=125mm.

All children in the three study arms will receive a weekly follow-up until meeting a discharge criterion.

Each cluster will correspond to one treatment provider (health centre or its group of CHWs) which means that there will be 6 groups of providers by arm. However, in order to avoid final real imbalance in cluster size, the unit of randomization will be the health centre with a block allocation ratio of 2:1:1.

Intervention Type
Supplement

Primary outcome measure
Data will be extracted directly from the patient records existing in the health centers and health huts at the end of the study:
1. Recovery rate: proportion of children achieving and maintaining the discharge criteria during two follow-up visits (two consecutive weeks)

2. Default rate: proportion of children absent of two follow-up visits (two consecutive weeks)
3. Decease rate: proportion of children who die during treatment or in transit to inpatient care
4. Referral rate: proportion of children referred to inpatient care due to the appearance of medical complications or nutritional treatment failure (non-response considered as oedema still present after 21 days, weight loss for two consecutive visits, not weight gain in 14 days, or failure in the appetite test)

Secondary outcome measures
1. Coverage compared at baseline and end-line from two population-based surveys conducted at the beginning and end following the standardized SLEAC methodology
2. Cost-effectiveness: cost per child treated and cost per child recovered. Financial information for the cost-effectiveness analysis will be taken towards the middle of the recruitment period using as a source the logistics and financial records of the Action Against Hunger offices and the health district authorities
Obtained monthly from the patient records:
3. Severity at admission (MUAC and WHZ measurements and oedema proportion)
4. Recovery time: time spent in treatment until being discharged as cured
5. Number of follow-up visit absent in those children recovered
6. Number of RUTF sachets consumed by those children recovered
7. Average weight and MUAC gain of those children recovered
8. Number of cases treated for other non-severe common diseases in an integrated manner (diarrhea, malaria, acute respiratory infection)

Overall study start date
01/07/2019

Completion date
27/09/2021

Eligibility

Key inclusion criteria
1. Children from 6 to 59 months of age
2. Diagnosed with uncomplicated severe acute malnutrition
3. Positive appetite test result
4. Without any medical danger sing (severe oedema, unable to drink or suck, severe vomit, convulsing, non-response to external stimuli, severe palmar pallor, severe difficulty breathing, spontaneous bleeding, dark urine, unable to sit/stand, severe diarrhea/dehydration)

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
The total sample size required is 1,728 (576 children per arm requiring 6 clusters, which accounts for 96 children per cluster). The sample size has been calculated for a binary result (recovered /not recovered) assuming a non-inferiority margin of 5%, with a power of 80%, sensitivity of 95%, 75% cure rate in the control group (according to SPHERE standards) and 85% cure rate in the intervention groups. The number of clusters required was calculated according to Hayes and Bennett's formula assuming 005 as the variation coefficient. It has been added a 10% of cases loss to follow-up.

Total final enrolment
1244

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2020

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
Mali

Study participating centre
Action Against Hunger (Action Contre la Faim, ACF)
Rue 254
Porte 637
Quartier Hippodrome
Bamako
Mali
BP E 2562

Sponsor information

Organisation
Complutense University of Madrid

Sponsor details

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Sponsor type
Research organisation

Website
https://webs.ucm.es/info/epinut/

ROR
https://ror.org/02p0gd045

Organisation
Institut National de Recherche en Santé Publique

Sponsor details
Route de Koulikoro
rue 235, porte 52
Hippodrome
Bamako
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1771
+223 20 21 42 31
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Sponsor type
Research organisation

Website
https://insp.ml/

ROR
https://ror.org/005haay02

Funder(s)

Funder type
Charity

Funder Name
Enhancing Learning and Research for Humanitarian Assistance

Alternative Name(s)
Enhancing Learning & Research for Humanitarian Assistance, ELRHA

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
United States Agency for International Development

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
We expect to publish at least two peer-reviewed articles in internationally recognized scientific journals with JCR impact (one focused on the intervention's effectiveness (outcomes and coverage) and another focused on the cost-effectiveness analysis). Results will be also disseminated through technical and scientific meetings and it will be included in the ACF newsletter on the iCCM+ strategy.

Intention to publish date
31/07/2023

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?
Protocol file		03/09/2019	05/09/2022	No	No
Protocol file		14/01/2020	05/09/2022	No	No
Results article		21/02/2024	17/04/2024	Yes	No
Other publications	Economic evaluation	20/01/2025	27/01/2025	Yes	No