

Treatment of severe acute malnutrition delivered by Community Health Workers in Niger

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| Submission date 31/07/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 03/08/2018 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 03/04/2024 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

In Niger, the prevalence of Global Acute Malnutrition (GAM) in children under 5 is consistently considered to be too high. This is particularly an issue in Mayahi, a town (department) in Niger. Several projects have been carried out to manage the problem of malnutrition; however, more than 50% of malnourished children still do not have access to treatment, with geographical and financial barriers being the key issues.

New strategies for the management of SAM (severe acute malnutrition) involve integrating this into the work of Community Health Workers (CHWs) in Mayahi, which brings the treatment closer to families, as CHWs often live in the same village as the families, removing the need to travel long distances or spend money on treatment.

This study aims to increase the number of children treated for SAM by CHWs, which will demonstrate the power of the CHW model in SAM management in Niger.

Who can participate?

Children aged 6-59 months with severe acute malnutrition

What does the study involve?

Children will be randomised into the intervention or control group. Both groups will receive the same treatment, including measurements of weight and upper arm circumference, along with ready to use therapeutic food. However, the intervention group will receive this from CHWs, whereas the control group will attend health centres. Both groups will receive treatment once per week for a year.

What are the possible benefits and risks of participating?

The benefit to children and their families in the intervention group is that they will no longer have to travel long distances and pay for transport to receive treatment for SAM. Participants in both groups will receive treatment for SAM. There are no known risks to participants taking part in this study.

Where is the study run from?

The study will be carried out in 2 areas in the district of Mayahi, at 10 health facilities and with 10 CHWs in both areas.

October 2017 to August 2019

Who is funding the study? (who will be paying the costs that the trial will incur during its lifecycle?)

USAID (USA)

Who is the main contact?

Pilar Charle Cuellar

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Niger Phase 1

Study information

Scientific Title

A cohort study comparing treatment for Severe Acute Malnutrition (SAM) in children between 6-59 months, delivered by Community Health Workers (CHWs) compared to a traditional facility based model in Mayahi district, Niger

Study objectives

Treatment of SAM by CHWs as part of the primary health package will:

1. Improve early identification of SAM cases compared to the Health Facility Treatment, with:
 - 1.1. Less complicated cases referred to a stabilisation center
 - 1.2. MUAC at admission closer to threshold levels
2. Improve access to treatment service in terms of coverage rates and barriers to access, as evaluated by SQUEAC assessments.
3. Not have an inferior effect on clinical outcomes of SAM treatment (including cure, death and in particular, defaulter rates)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Le Comite National D'Ethique pour la Recherche en Sante of Niger, Niamey, 29/03/2018, DELIBERATION No 007/201 8/CNERS

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Severe acute malnutrition

Interventions

The study is carried out in two areas within the district of Mayahi with similar sociodemographic, cultural and education characteristics.

Disease prevalence is matched to create 2 groups: Guidan Amoumoun (intervention) and Maireyrey (control), which are randomly allocated to receive the intervention or treatment as usual.

Intervention groups have community health workers in place to deal with issues. They are

trained to deliver the same treatment as centres - diagnosis, providing ready to use therapeutic food sachets (RUTF sachets) and discharge from care, with all admissions recorded. Participants in control groups continue with usual treatment. Mothers of the malnourished participants take them to health centres for diagnosis of SAM and treatment. These visits are usually weekly, to monitor growth whilst receiving RUTF sachets until discharge. Participants are followed up weekly until discharge, with measurements obtained from clinical data records for assessment. In total, the trial will last for 18 months.

Intervention Type

Other

Primary outcome measure

The following performance indicators will be measured using the clinical and individual data obtained from ongoing care for the patients through the reporting system and procedures, including the children monitoring cards:

1. Cure rate, assessed at every visit to the health facility or with the CHW (weekly basis), defined as:
 - 1.1. Weight-to-height ratio > 1.5
 - 1.2. MUAC (mid-upper arm circumference) > 125 cm
2. Death rate, determined over the course of the study
3. Defaulter rate - if children do not attend visits on 2 consecutive weeks, they are discharged as defaulters

Secondary outcome measures

Coverage of the interventions is measured using coverage assessment using the SQUEAC methodology (Semi-Quantitative Evaluation of Access and Coverage) in both areas at the baseline and at the end of the study. SQUEAC uses the following 3 stages:

1. Identification of low or high coverage areas, along with factors negatively influencing coverage by using routine data for the program and qualitative data gathered from key informers, with the goal of ensuring triangulation and exhaustiveness of sources and methods
2. Confirmation of low and high coverage areas, and of the factors explaining low coverage identified in stage 1
3. Estimation of program coverage using the Bayesian technique

Overall study start date

01/10/2017

Completion date

01/08/2019

Eligibility

Key inclusion criteria

1. Age 6 to 59 months
2. Diagnosed with SAM according to any of the following criteria:
 - 2.1. MUAC < 115 mm
 - 2.2. Bilateral edema
 - 2.3. Weight-to-height ratio < -3 Z-score
3. Parents or guardians can provide informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

59 Months

Sex

Both

Target number of participants

700

Total final enrolment

2789

Key exclusion criteria

1. Residence outside the study areas
2. Complications that require treatment in the stabilization center in Mayahi

Date of first enrolment

01/05/2018

Date of final enrolment

01/05/2019

Locations

Countries of recruitment

Niger

Study participating centre

Action Against Hunger

Mayahi

Niger

BP 11491

Sponsor information

Organisation

Action against Hunger

Sponsor details

Calle duque de Sevilla nº3
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Sponsor type

Charity

Website

<https://www.accioncontraelhambre.org/es>

ROR

<https://ror.org/01ndqne76>

Funder(s)**Funder type**

Not defined

Funder Name

OFDA <https://www.usaid.gov/who-we-are/organization/bureaus/bureau-democracy-conflict-and-humanitarian-assistance/office-us>

Results and Publications**Publication and dissemination plan**

We aim to publish in one of the following peer-reviewed journals:

1. BMC Nutrition
2. Journal of Health, Population and Nutrition
3. Health Policy and Planning
4. Public Health Nutrition

We also expect to participate in the following conferences:

1. Africa Epidemiological and Nutrition Conference
2. Core Group Global Health Practitioner Conference

Intention to publish date

31/03/2022

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made 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? |
|------------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 14/11/2021 | 05/09/2022 | Yes | No |
| Other publications | | 29/03/2024 | 03/04/2024 | Yes | No |