ISRCTN31143316 https://doi.org/10.1186/ISRCTN31143316

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

Submission date
31/07/2018

Recruitment status
No longer recruiting

Registration date
03/08/2018

Overall study status
Completed

Last Edited
03/04/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
pcharle@accioncontraelhambre.org

Contact information

Type(s)
Scientific

Contact name
Mrs Pilar Charle Cuellar

ORCID ID
https://orcid.org/0000-0003-4784-5003

Contact details
Calle duque de Sevilla nº3
Madrid
28002
Spain
Madrid
Spain
28002
34 91 184 0845
pcharle@accioncontraelhambre.org

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

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(s)
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 healthy 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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
All

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

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

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