

Treatment for severe acute malnutrition delivered by community health workers in Mali

Submission date 02/03/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/10/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Action Against Hunger (ACF) has intervened in Mali since 1996. ACF is involved in the district of Kita since 2007 through the Project for Improving Food and Nutrition Security in the four communes of the south.

In the food and nutrition crisis of 2012, ACF expanded to support all areas of functional health district through the project "Strengthening local capacities for integrated management of acute malnutrition and access to food in Kita". 35 health areas spread over 29 communes receive technical and material support for the management of severe acute malnutrition. Cases of uncomplicated SAM are supported at the Health Reference Centre, and those with complications at St. Felix Centre in Kita.

Management of moderate acute malnutrition happens at two levels: at the community health centre, but also at the community level in villages with Community Health Workers (CHWs). These are health workers based in some villages with no community health centre: they offer a package of basic preventive and curative care. In each health area, an additional network of community volunteers implement screening activities. In spite of the many advantages and successes of this approach, a recent coverage assessment carried out by ACF in March 2013 determined that facility-based treatment in Kita was estimated to be reaching around 25% of the affected population. Awareness and distance from centres (can be several hours walking) were found to be major barriers to access preventing caregivers from accessing care. The need for stronger links with the community were identified as key areas of improvement.

This study aims to examine the impact of integrating treatment and early identification of SAM with the basic package delivered by the CHWs in several communes of the "cercle" of Kita where ACF supports the community-based management of acute malnutrition, currently delivered at health centre level. This aims to provide evidence that will help to support integration of SAM treatment into existing healthcare packages delivered by Community Health Workers and provide a model capable of bridging some of the most common barriers to access faced by traditional service delivery models.

Who can participate?

Children aged 6 to 59 months with severe acute malnutrition.

What does the study involve?

Participants within selected areas are allocated to one of two groups. These groups are then randomly assigned to receive the intervention, or treatment as usual.

Those in the intervention group have community health workers available to provide care (diagnosis, treatment with food sachets and weekly follow up) at their door.

Those in the control group are taken to health centres by their mothers for treatment.

Participants are followed up weekly until discharge, and have clinical data recorded at each appoint for assessment.

What are the possible benefits and risks of participating?

Participants may benefit from receiving care at their door and avoiding long travel to clinics.

There are no direct risks to participants.

Where is the study run from?

Communes in Kita (Mali)

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

August 2014 to November 2017

Who is funding the study?

Innocent Foundation (UK)

Who is the main contact?

Dr Jose Luis Alvarez Moran (Scientific)

Contact information

Type(s)

Scientific

Contact name

Dr Jose Luis Alvarez Moran

ORCID ID

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

INNOA1

Study information

Scientific Title

A cohort study comparing treatment for Severe Acute Malnutrition (SAM) delivered by Community Health Workers compared to a traditional facility based model

Study objectives

Treatment of SAM by ASCs as part of the SEC package will:

1. Improve early identification of SAM cases compared to the Health Facility Treatment with less complicated cases referred to SC and MUAC at admission closer to threshold levels.
2. Improve access to treatment service: coverage rates and barriers to access as evaluated by SQUEAC assessments.
3. Improve cost-effectiveness compared to treatment at health facilities.
4. Provide high quality of care (>80% error-free case management).
5. 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)

Ethics Committee of the National Institute for Research in Public Health (Comité d'Ethique de l'Institut National de Recherche en Santé Publique) Mali, 13/01/2015, ref: 03/2015/CE-INRSP

Study design

Randomised 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Malnutrition

Interventions

Areas within the 'circle' of Kita with similar sociodemographic, cultural and education characteristics and disease prevalence are matched to create two groups: Group Kita East and Group Kita West. These are randomly allocated to receive the intervention or treatment as usual. Intervention areas have community health workers in place to deal with issues. They are trained to deliver the same treatment as centres: diagnosis, giving RUTF and discharging from care, with all admissions recorded.

Participants in control areas continue with usual treatment. Mothers of the malnourished participants take them to health centres for diagnosis of SAM and treatment, usually weekly visits to monitor growth whilst receiving treatment of ready to use therapeutic food sachets (RUTF) until discharge.

Participants are followed up weekly until discharge with measurements obtained from clinical data records for assessment.

Intervention Type

Supplement

Primary outcome measure

Performance indicators (cure rate, defaulters and death rate) are 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.

Secondary outcome measures

Coverage of the interventions is measured using coverage assessment in both areas.

Overall study start date

01/08/2014

Completion date

30/11/2017

Eligibility

Key inclusion criteria

1. Age 6 to 59 months. Parents are asked to show the surveyors a proof of age, if this is not possible the surveyors use an events calendar to ensure that the age stated by the parents was correct. Height is not used as a proxy indicator for age.
2. Diagnosed with SAM according to any of the following criteria:
 - 2.1. MUAC <115mm
 - 2.2. Bilateral edema
 - 2.3. W/H <-3 z-score
3. Ability of the parents or guardians to 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

600

Total final enrolment

934

Key exclusion criteria

1. Residence outside the study areas
2. Complications that required treatment in the stabilization center in Kita (URENI)

Date of first enrolment

16/02/2015

Date of final enrolment

15/02/2016

Locations

Countries of recruitment

Mali

Study participating centre

Kita

Mali

-

Sponsor information

Organisation

Innocent Foundation

Sponsor details

342 Ladbroke Grove

London

United Kingdom

W10 5BU

Sponsor type

Industry

Website

<https://www.innocentfoundation.org/about-us>

Funder(s)

Funder type

Charity

Funder Name

Innocent Foundation

Results and Publications

Publication and dissemination plan

Intention to publish in BMC Health Services Research in 2018.

Intention to publish date

31/08/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from Dr Alvarez Moran or Alexandra Rutishauser-Perera, A.
RutishauserPerera@actionagainsthunger.org.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/03/2018		Yes	No
Results article		05/04/2017	06/10/2022	Yes	No
Results article		20/02/2018	06/10/2022	Yes	No