

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

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

<http://orcid.org/0000-0003-1930-5659>

### Contact details

Action Against Hunger UK

1st Floor, Rear premises 161-163

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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](mailto:RutishauserPerera@actionagainsthunger.org.uk)

**IPD sharing plan summary**

Available on request

**Study outputs**

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