ISRCTN14990746 https://doi.org/10.1186/ISRCTN14990746

Comparison of three models of training and supervision with community health workers providing treatment of children with severe acute malnutrition in Mali

Submission date
20/03/2018

Recruitment status
No longer recruiting

Registration date
20/04/2018

Overall study status
Completed

Last Edited
06/05/2025

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
The aim of the trial is to find out how to most effectively increase coverage of severe acute malnutrition treatment (SAM) with Community Health Workers (CHWs). An implementation study will carried out in Mali, in three districts of Kayes Region , Kita, Kayes and Bafoulabé. Total population in the study area is 1415405 inhabitants with 283061 children under five. Prevalence of severe acute malnutrition (SAM) in the area is 2.6% according to the last SMART survey (high prevalence and serious is situation) , and coverage of SAM treatment (SQUEAC survey) was low (<30%). Specific objectives include comparing the effectiveness of SAM treatment for the three different intervention methods (cured rate, discontinuation rate, death rate), comparing the coverage (early and late admission) of SAM treatment for the three different methods, comparing the employment time of CHWs in the three different methods, comparing the cost-effectiveness of SAM treatment by CHWs in the three different methods and identifying the most efficient way of scaling up SAM treatment by CHWs

Who can participate?
All of the children aged 6 months to 5 years who visit the health facility and/or to the CHWs and have the diagnosis criteria for SAM without complications will be included in the study. Case of SAM is defined as Midd Upper Arm Circumference (MUAC) < 115 mm or bilateral edemas, and no danger symptoms. Families should agree and informed consent will be signed.

What does the study involve?
In the three models all the children involved in the study will receive the same treatment and will be followed up according to the national protocol of severe acute malnutrition management. Caregivers should bring their children once a week during the whole duration of the treatment, normally 2 months. At each visit, children will be evaluated, take measure of MUAC and evaluation of dangers symptoms. Families will receive treatment (RUTF, ready to use therapeutic food) for a week.
Children recruitment and follow-up will be during a period of 12 months at the health facilities

and with CHWs. All the children admitted with the diagnosis of SAM will be follow up during 2 months in a weekly bases, until they achieved discharges criteria (cured, defaulters or deaths). Over the period together with the children recruitment other complementary studies will be developed in the three areas. The use of CHWs' time analysis will be done during the months of highs admission for nutrition. The cost-effectiveness analysis will give evidence to the Ministry of Health how to scale up the strategy in the country.
According to the policy of Primary Health care in Mali, the responsibility for supervising a CHW site first falls to the technical team of the health facility, and particularly to the Centre's Technical Director. The district, regional and central levels of supervision are responsible for providing the health facility teams with the technical support necessary to build their capacities in supervision of the CHWs sites. Normally this policy is not followed up in the field because of lack of budget allocated to these activities.
We will have three different level of supervision: i) Health District of Kita: High Intensity Operational Framework. With the financial and logistic support from Action against Hunger (AAH) , the CHWs will received supervision from the health facility, district level and one specific nutrition supervision from the AAH team ii) Health District of Kayes: Low intensity Operational Framework. With financial and logistic supervision from AAH, the CHWs will receive supervision from the health facility and district level. No specific supervision in nutrition from AAH team. Bafoulabé model: No support from AAH for CHWs supervision.

What are the possible benefits and risks of participating?
The most important benefit for the participants is the closer distance to their own villages. One of the main barriers identifed as a barrier to receive treatment for SAM is the geographical and economical barrier to the health facility. Families have to walk for more than 2 hours to bring children to the health facility or pay money for the transport, that most of the time they do not have. CHWS are normally in the own villages, they can found them at any time, and it is easy to receive the treatment every week, without expend any money.
We are not expecting to have any side effects, as the treatment used and also the protocol is the same, as the children who are receiving the treatment at health facilities.

Where is the study run from?
The study will be developed in the areas where the Ministry of Health is working, a total of 164 CHWs and 115 health facilities in the three districts. As the number of population is different in the three districts we will have: Kita, 47 health facilities and 80 CHWs; Kayes, 49 health facilities and 45 CHWs; Bafoulabé, 19 health facilities and 39 CHWs.

When is the study starting and how long is it expected to run for?
The intervention will take place from January 2017 to December 2018, over a period of 24 months. The project will be implemented by ACF in close collaboration with the National Health Directorate (DNS) and the National Institute of Public Health (INRSP). Evaluation will be conducted externally (INRSP and consultants).

Who is funding the study?
All the cost including human resources recruitment, training of the staff from the Ministry of Health, logistic for supervision and results dissemination and publications, will be with funding from the Innocent Foundation and People’s Post Code Lottery

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
MALI PHASE 2

Study information

Scientific Title
Effect of integrating the management of severe acute malnutrition without complications into essential community healthcare with community health workers in the Kita, Kayes and Bafoulabé health districts in Mali

Study objectives
We hypothesize that providing community health workers (CHWs) with the appropriate training and supervision for the treatment of severe acute malnutrition (SAM) will contribute to:
1. An increase in SAM treatment coverage for the different methods after 12 months of intervention.
2. An improvement in the quality of SAM treatment in accordance with the Management of Malnutrition Protocol (recovery rate, death rate and discontinuation rate).
3. A good evaluation of SAM treatment time by CHWs.
4. A more cost-effective method than increasing SAM treatment coverage.
5. Identifying the most efficient way of scaling up SAM treatment by CHWs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
President of the ethical committee from the Institute National de Recherche et Sante Publique (INRSP) in Bamako, Mali, 30/06/2017, 13/2017 CE INRSP.

Study design
Interventional cohort study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Malnutrition

Interventions
The study is carried out in the three districts of Kayes: Kita, Kayes and Bafoulabe, with similar sociodemographic, cultural and education characteristics. In the three areas SAM treatment will be delivered at the health facilities and by CHWs. CHWs are trained to identify, diagnosis, follow up and treat SAM children aged 6 months to 5 years with ready-to-use therapeutic food (RUTF). Participants (children and mothers/caregivers) visit the CHWs on a weekly basis. CHWs follow up the weight, the mid upper arm circumference (MUAC) and identify dangers symptoms of all the children. They follow the admission and discharge criteria of the National Protocol of Management of severe acute malnutrition.

Training will be conducted in each of the three models. Training was done using the "cascading" method. Thus, national trainers trained regional trainers as well as those at the health district level. The health district trainers will in turn train the DTCs and CHWs with support from the regional trainers in all three methods. Training of CHWs will be conducted in accordance with the national guide on implementation of the revised SECs. Following this initial training, the CHWs in all three methods will do a six week practical internship on SAM treatment. The goal of this internship is to ensure each CHW is able to offer high quality SAM treatment in accordance with the national IMAM protocol. The following method will be used. Under direct supervision from the DTC or nutrition program officer, they will do a three week internship in a CSCOM on SAM treatment days. Under direct supervision from the DTC or nutrition program officer, the CHW will perform SAM treatment on his own site for three weeks. These internships will follow an Integrated Management of Acute Malnutrition (IMAM) practical internship guide adapted to CHWs. An evaluation of CHWs will be conducted on the last session of SAM treatment following an IMAM evaluation grid adapted for this purpose.

The goal of the CHW supervision is to strengthen the technical and logistical capacities of CHWs to ensure high quality care and the optimal performance of the SEC approach. The supervision will focus on post-training monitoring, as well as on the monitoring of activities, the operation of the CHW site, the correct maintenance of support documentation, input management and the coordination and holding of meetings. Supervision of the CHW by the DTC is carried out monthly. Supervision by the management team of the district and by the regional level team is generally carried out during the integrated quarterly supervisions. Those at the central level are carried out bi-annually. For various reasons (limited human, financial and logistical resources), these different supervisions are not carried out.

This study will test three methods of supervision:
1. Method 1: Health District of Kita (Kita, Sagabari and Sefeto), High Intensity Operational Framework
Supervision Method: With the logistical, financial and human resources (HR) support from Action Against Hunger, the following supervisions will be carried out (47 health facilities and 80 CHWs)
1.1. Monthly supervision of the CHWs by the nurse responsible of the health facility
1.2. Quarterly supervision of the health facility and CHW sites by the management team of the district
1.3. Bi-annual supervision of the health districts, the health facility and the CHWs at the regional

and central levels
1.4. Nutrition-specific monthly supervision of the CHWs by three doctors appointed in support of the nutrition focal points and primary health care.

2. Method 2: Health Districts of Kayes, Low Intensity Operational Framework
Supervision Method: With the logistical, financial and human resources (HR) support from Action Against Hunger, the following supervisions will be carried out (49 health facilities and 45 CHWs)
2.1. Monthly supervision of the CHWs by the nurse responsible of the health facility
2.2. Quarterly supervision of the health facility and CHW sites by the management team of the district
2.3. Bi-annual supervision of the health districts, the health facility and the CHWs at the regional and central levels
2.4. No specific supervision in nutrition management

Method 3: Health District of Bafoulabé
Without technical and financial support from Action against Hunger, supervision of the 19 health facilities and the 39 CHWs will be done in accordance with the revised primary health care tools.
3.1. Bi-annual supervisions: the DNS, in collaboration with the DRS and district's management team will supervise the activities of the 39 CHW sites and the 19 CSCOMs.
3.2. Quarterly supervisions: the district management team will supervise all 39 CHW sites at least once per quarter.
3.3. Monthly supervision: the CSCOM teams will supervise all of their CHW sites at least once a month.

Intervention Type
Behavioural

Primary outcome(s)
1. Percentage of children with MUAC >125 mm
2. Percentage defaulters (children who have missed two consecutive CHW/health facility visits)
3. Percentage of children who die during treatment period
Data will be reported on a monthly basis by CHWs and health facilities. The normal length of treatment is 6-8 weeks.

Key secondary outcome(s))
1. Workload of CHW
Time allocation for all three methods, and on the distribution of time between preventative activities and curative activities, as well as the average time required for a CHW to manage a SAM case in all three methods will be recorded. We evaluated the different timetable tools which provide precise estimations of contact time for the health workers. The gold standard for studies on time use is direct observation and study of time allocation with the help of highly qualified observers. However, this method requires enough resources, not only in terms of time required for a sufficient number of observations, but also in terms of qualified staff to carry out these observations, and in terms of local expertise, which is often rare for these methods (and which means recruiting international experts is sometimes required). Previous research suggests that self-administered time logs are an alternative method. It provides estimations of the duration of contact between the health worker and his patients through direct observations. The analysis is expected in July 2018.
2. Cost-effectiveness
Any healthcare strategy must take into account costs and effectiveness. A retrospective study will be carried out during the second phase of the project. Data on costs supported by Action

Against Hunger will come from Action Against Hunger's accounting statements. The program's other costs, including those supported by the government's healthcare facilities, will be collected through interviews with key informers, conducted by the study coordinator. Costs which are not available through accounting records will be estimated using a method based on ingredients, using unit costs and various input quantities. Household costs will be estimated by discussion groups in each study area. The variation of these costs will be modelled using sensitivity analysis. Interviews regarding timetables will be conducted with most employees involved in the implementation of the project (including estimations from the study of time use by CHWs) in order to carry out an analysis of costs based on activity. The analysis is expected in September 2018.

Completion date
01/01/2019

Eligibility

Key inclusion criteria
1. Aged 6-59 months
2. SAM defined in accordance with the Integrated Management Acute Malnutrition protocol, taking into account one of the following criteria: MUAC <115 mm or bilateral oedema
3. Parents have given their voluntary and informed consent to participate in the study

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
6112

Key exclusion criteria
1. Complications requiring treatment in a unit for intensive nutritional rehabilitation (URENI)
2. Trips outside of the intervention area

Date of first enrolment
01/11/2017

Date of final enrolment
01/11/2018

Locations

Countries of recruitment
Mali

Study participating centre
Kita, Kayes, Bafoulabe
Mali
1035

Sponsor information

Organisation
Action against Hunger

ROR
https://ror.org/01ndqne76

Funder(s)

Funder type
Not defined

Funder Name
Innocent Foundation

Funder Name
People's Post Code Lottery

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/01/2021	16/02/2021	Yes	No
Results article		21/10/2022	24/10/2022	Yes	No
Other publications	Economic evaluation	27/06/2024	06/05/2025	Yes	No
Protocol file	in French	22/06/2017	07/09/2022	No	No