ISRCTN50039021 https://doi.org/10.1186/ISRCTN50039021

Modelling an alternative nutrition protocol generalizable for outpatient (MANGO)

Submission date
13/04/2016

Recruitment status
No longer recruiting

Registration date
13/05/2016

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Severe acute malnutrition in children under 5 is defined by being too thin for a given height and /or having the left arm circumference less than a given threshold (i.e. measuring how fat or thin the arm is), and/or having swollen feet (malnutrition oedema). It affects 19 million children under five at any point in time, and is likely to result in death if left untreated. Children can be treated in the hospital as in inpatient (hospitalized, for example, due to medical complications) or as outpatients, coming once a week to the closest health centre for monitoring and to receive treatment that they take at home. A very effective ambulatory (outpatient) treatment has been in place for several years and involves giving each patient an antibiotic and a therapeutic food made of peanut paste, vegetable oil, powdered milk, sugar, vitamins and minerals. The amount given to each child is matched to their individual nutritional needs. The treatment does work, however the children do gain less weight than expected. There have been reports that this may be partly due to the therapeutic food being shared with the family and it being sold on the market. It is also possible that malnourished children in the process of recovery may need less therapeutic food than currently provided. This study will test out this theory by giving children treated as outpatients a lesser amount of the therapeutic food to see whether they still gain the weight. Other effects of the treatment from admission to discharge will also be measured, including duration of the treatment, the recovery, how many stick with the treatment, how many are admitted to hospital, death and relapse rates from the nutritional programme, the changes in anthropometry (weight, height, arm circumference, leg length), average energy intake after 4 weeks of treatment, micronutrient blood status changes (that is, levels of nutrients in the blood), hair changes, body fat and lean masses changes. The cost of treatment will also be calculated and compared with costs for children given the more standard amount of therapeutic food.

Who can participate?
Children aged 6 to 59 months, diagnosed with severe acute malnutrition, without malnutrition oedema, without medical complications and having passed successfully an appetite test.

What does the study involve?
The children are randomly allocated to one of two groups. Those in group 1 are given the standard amount of therapeutic food. Those in group 2 are given the reduced amount of

therapeutic food. For the first two weeks of treatment, all children are given the same amount. From week three, however, children in group 2 are given a reduced amount until their discharge from care. All children are also given the same basic medical treatment for the management of severe acute malnutrition.

What are the possible benefits and risks of participating?
All children will benefit of getting treatment for malnutrition. However, children in both groups may not gain a lot of weight, if any at all. They may also suffer from fever, diarrhea, cough, etc. which are all danger signs that means they have to be referred to hospital for treatment under 24-hour care, as per standard protocol. For the reduced dosage group, referral will be considered towards returning to a standard dosage, or to hospital, depending of the clinical assessment.

Where is the study run from?
The study will be run in 10 health centres of Fada N'Gourma district, located in the Eastern Region of Burkina Faso.

When is the study starting and how long is it expected to run for?
September 2015 to December 2017

Who is funding the study?
1. Children's Investment Fund Foundation (CIFF)
2. European Commission's Humanitarian aid and Civil Protection Department (ECHO)
3. Humanitarian Innovation Fund (HIF)

Who is the main contact?
Mrs Cécile Salpéteur (public)
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Study information

Scientific Title
Modelling an Alternative Nutrition Protocol Generalizable for Outpatient (MANGO) - effectiveness of an optimized dosage of RUTF for the treatment of severe acute malnutrition: a randomized controlled, non-inferiority trial in Burkina Faso

Acronym
MANGO Project

Study objectives
The proposed study hypothesizes that a reduced dose of RUTF starting at the third week of treatment among severely acutely malnourished children would result in equal weight gain and recovery from malnutrition as when children are receiving a full dose of RUTF throughout the treatment period. This hypothesis is based on the assumption that the full dose of RUTF is not consumed entirely by the malnourished child but shared with other family members or even sold. This assumption is based on various field observations and backed up by program data indicating a slower recovery than expected when considering the energy provided by the RUTF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee on Health research of the Ministry of Health of Burkina Faso, 02/12/2015, ref: 2015-12-01

Primary study design
Interventional

Study design
Randomized controlled non-inferiority trial using individual randomization to allocate patients to either the intervention arm or control arm.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-complicated severe acute malnutrition among children 6-59 months.

Interventions
The intervention tested is restricted to the nutritional treatment of malnourished children involving ready-to use therapeutic foods (RUTFs). The nutritional treatment protocol will be different between the 2 study groups. For the first 2 weeks of treatment, both the intervention and the control arm receive a standard dose of RUTF as per national protocol. However, from the third week onwards the intervention arm will receive a reduced dose while the control arm will continue on the full dose of RUTF. This will continue until discharge. The basic medical treatment of the children will be the same between the 2 groups and will follow the recommendations for the management of severe acute malnutrition as per the national protocol. The nutritional treatment scheme for the 2 groups is described below.

Ration scheme

Normal dose RUTF:
Week 1 to discharge
Weight (kg) Sachets/wk Kcal/kg/d
3.0-3.4 8 168-190
3.5-4.9 10 183-204
5.0-6.9 15 155-214
7.0-9.9 20 144-204
10.0-14.9 30 144-214

Optimised dose RUTF:
Week 1-2 Week 3 to discharge
Weight (kg) Sachets/wk Kcal/kg/d Sachets/wk Kcal/kg/d
3.0-3.4 8 168-190 7 147-167
3.5-4.9 10 183-204 7 102-143
5.0-6.9 15 155-214 7 72-100
7.0-9.9 20 144-204 14 101-143
10.0-14.9 30 144-214 14 67-100

Intervention Type
Other

Primary outcome(s)
Childrens rate of weight gain (g/kg/d) during treatment, measured at admission, upon weekly visits, and at discharge.

Key secondary outcome(s)
1. Duration of treatment (days) until recovery
2. Recovery rate, defaulter rate, mortality rate and transfer to hospital rate, measured monthly
3. Growth velocity and change in anthropometry (weight for height, height for age, weight for age, Mid Upper Arm Circumference), measured on a weekly basis from admission to discharge, and with monthly follow-up measurements during 4 months
4. Relapse rate 4 months after discharge
5. Cost-effectiveness ratio of the intervention to rehabilitate one child
6. Average energy intake (kcal/d) of the child during treatment week number 4
7. Level of vitamin A, iron and inflammation markers in the blood, measured at admission and discharge dates
8. Body composition status at admission and discharge, measuring bio-impedancemetry
9. Level of leptin in the blood, measured at admission, and discharge
10. Catabolism markers in hair, measured at admission, and last follow-up 4 months after discharge

Completion date
01/02/2019

Eligibility

Key inclusion criteria
1. Children aged 6 to 59 months
2. Diagnosed with uncomplicated SAM and eligible for CMAM treatment, defined as WHZ <-3 and /or MUAC <115mm
3. No pitting bilateral oedema

4. No medical complications
5. Passed a standardized appetite test

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
801

Key exclusion criteria
1. Severe anaemia defined as haemoglobin concentration < 4g/dl
2. Plans to leave the catchment area within the next 6 months
3. Known peanut and/or milk allergy
4. Treatment for SAM already received within the last 6 months, including re-admissions after defaulting, relapses, and medical transfers
5. Malformations or handicap which may affect food intake such as cleft palate, cerebral palsy or Down's syndrome

Date of first enrolment
17/10/2016

Date of final enrolment
20/07/2018

Locations

Countries of recruitment
Burkina Faso

Study participating centre
Health centres located in Health district of Fada N'Gourma, East of Burkina Faso
Burkina Faso
N/A

Sponsor information

Organisation
ACF France

ROR
https://ror.org/035j0tq82

Funder(s)

Funder type
Charity

Funder Name
Children's Investment Fund Foundation (CIFF)

Funder Name
European Commission's Humanitarian aid and Civil Protection Department (ECHO)

Funder Name
Humanitarian Innovation Fund (HIF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Cécile Salpéteur (csalpeteur@actioncontrelafaim.org)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/08/2019	16/12/2019	Yes	No
Results article	results	01/11/2020	12/02/2021	Yes	No

Results article	results	01/11/2020	12/02/2021	Yes	No
Results article	results	11/02/2021	12/02/2021	Yes	No
Results article		23/02/2021	11/08/2021	Yes	No
Results article		01/06/2021	11/08/2021	Yes	No
Other publications	predictors of time to recovery and non-response	31/05/2022	09/07/2024	Yes	No
Other publications	sub-study vitamin B12 status	08/08/2023	09/07/2024	Yes	No
Protocol (other)			02/09/2022	No	No
Statistical Analysis Plan			02/09/2022	No	No