ISRCTN15258669 https://doi.org/10.1186/ISRCTN15258669

Effectiveness of a reduced dose of ready-to-use therapeutic food (RUTF) in the management of uncomplicated severe acute malnutrition (SAM)

Submission date
11/09/2021

Recruitment status
No longer recruiting

Registration date
25/01/2022

Overall study status
Completed

Last Edited
19/05/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
More than 47 million children were acutely malnourished worldwide before the COVID-19 pandemic. Disruptions in economic systems, reduced access to health and nutrition services have led to a 20% increase (about 10.4 million) in the number of children who will be acutely malnourished by 2021, mainly in low- and middle-income countries (Asia and Sub-Saharan Africa, including the Democratic Republic of Congo (DRC)).
The treatment of severe acute malnutrition (SAM) without complications is done on a community basis using systematic medical and nutritional treatment (distribution of Ready-to-use Therapeutic Foods, RUTF) according to the strategy of community-based management of acute malnutrition (CBM).
The aim of this study is to evaluate the effectiveness of a reduced dose of RUTF on the velocity of weight gain in children aged 6-59 months suffering from severe acute malnutrition.

Who can participate?
All medically uncomplicated SAM children aged 6-59 months.

What does the study involve?
Children enrolled in this study will be divided into two groups: control and intervention. For the first 2 weeks, all children in both groups will receive the same dose of standard RUTF. From the third week onwards, the dose of RUTF will be reduced for the intervention group according to their weight.

What are the possible benefits and risks of participating?
The child will be treated against malnutrition and will receive the same care as that usually provided by the health center. The risks are no weight gain, weight loss or allergies to the products used in the manufacture of the Ready-to-Use Therapeutic Food. In case of risk, the study is covered by insurance and the principal investigator will ensure the treatment and compensation of any adverse effect observed in the child following this study, linked to the use of the nutritional product and/or research procedures, throughout the duration of the study.

Where is the study run from?
Université de Kinshasa (DRC)

When is the study starting and how long is it expected to run for?
February 2021 to August 2022

Who is funding the study?
Foreign, Commonwealth & Development Office (FCDO) of the UK Government (updated 28/03/2022, previously: Action Against Hunger (DRC); updated 31/01/2022, previously: Foreign, Commonwealth & Development Office (FCDO) of the UK Government)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Effectiveness of a reduced dose of ready-to-use therapeutic food (RUTF) in children under 5 years of age suffering from uncomplicated severe acute malnutrition (SAM) compared to a standard dose: a randomized, controlled, non-inferiority trial in real-life conditions in Bonzola and Nzaba Health Zones, city of Mbuji-Mayi, Kasai Oriental, DRC, in 2021

Acronym
EfRAMAS

Study objectives

Children receiving the reduced dose will have the same weight gain from admission to discharge as children receiving the standard dose of Ready-to-Use Therapeutic Food (RUTF) with a non-inferiority margin of 0.5 g/kg/d.

Secondary assumptions :
1. Children receiving the reduced dose of RUTF will have the same performance indicators (cure rate, death, dropout, relapse) as those receiving the standard dose
2. Children receiving the reduced dose of RUTF will have the same length of stay as those receiving the standard dose
3. Children receiving the reduced dose of RUTF will have the same psychomotor development as those receiving the standard dose
4. Treatment with the reduced protocol of RUTF will be less expensive than treatment with the standard dose.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/07/2021, Ethics Committee of the School of Public Health, University of Kinshasa (Campus Université de Kinshasa, DRC; +243 817 493 194; espsec_unikin@yahoo.fr), ref: ESP/CE /127/2021

Study design
Interventional randomized controlled non-inferiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe acute malnutrition without medical complications

Interventions
Current intervention as of 31/01/2022:
This study is a non-inferiority randomized controlled trial. Randomization will be done at the individual level in each of the 14 study health areas. Block randomization of varying sizes will be used. After randomization, participants will be randomly assigned to either the control or intervention group. Each participant will receive the dose of RUTF corresponding to the group to which he/she belongs: standard dose for the control group and reduced dose for the intervention group. Both groups will receive the same dose of RUTF for the first 2 weeks. Then in the intervention group, the reduction in the dose of RUTF will occur from the third week of treatment. The intervention will be started concomitantly in both groups. The dose reduction will range from 13 to 53% depending on weight. In addition to nutritional management, participants will also receive routine medical treatment.

After recovery (according to the admission criteria, if P/T ≥- 1.5 z-score at two consecutive weighings, and PB ≥125 mm and absence of nutritional oedema for 14 days), follow-up of participants will be performed every 15 days until 3 months after discharge as planned in the national protocol. During this follow-up, the children will receive medical treatment if needed

according to symptoms (malaria, etc) and a nutritional product (fortified flour or Ready-to-use Supplementary Food [RUSF]) if available. Children who develop complications during treatment will be referred to the Intensive Therapeutic Nutritional Unit (UNTI) and then reintegrated into their study group after the complication has been resolved.

During the course of the study, a qualitative survey using focus groups, in-depth interviews, and field observations will assess the degree of acceptance of the reduced dose of RUTF by the local communities. An economic evaluation of the cost of treatment will be done during the study by comparing the reduced dose approach to the standard dose approach.

A sub-study will document the evolution of the Psychomotor Development (DPM) status of children from admission to discharge and at 6 months follow-up. This sub-study aims to assess the proportion of children with psychomotor developmental delay (PDD) and to monitor their progress during treatment. Psychomotor developmental delay (PDD) refers to impairments in the acquisition of skills and competencies in the areas of language, cognitive, motor, and social interaction. PDD corresponds to a score of less than 70% in two of the four domains of Psychomotor Development (DPM).

Previous intervention:
This study is a non-inferiority randomized controlled trial. Randomization will be done at the individual level in each of the 14 study health areas. Block randomization of varying sizes will be used. After randomization, participants will be randomly assigned to either the control or intervention group. Each participant will receive the dose of RUTF corresponding to the group to which he/she belongs: standard dose for the control group and reduced dose for the intervention group. Both groups will receive the same dose of RUTF for the first 2 weeks. Then in the intervention group, the reduction in the dose of RUTF will occur from the third week of treatment. The intervention will be started concomitantly in both groups. The dose reduction will range from 13 to 53% depending on weight. In addition to nutritional management, participants will also receive routine medical treatment.

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Intervention Type
Supplement

Primary outcome(s)
Current primary outcome measure as of 25/03/2022:
Weight gain velocity (g/kg/d) measured using scales weekly from admission to discharge

Previous primary outcome measure as of 31/01/2022:
Weight (kg) measured using scales weekly between admission and discharge, and then fortnightly after discharge for up to 3 months

Previous primary outcome measure:
Weight (kg) measured using scales at admission, at discharge, and then every 15 days up to 3 months

Key secondary outcome(s))

Current secondary outcome measures as of 31/01/2022:
1. Acceptance of a reduced dose during SAM treatment by health care personnel and the community measured using discussion groups, in-depth interviews, and direct observation using interview and focus group guides as well as observation grids in November 2021. This survey will assess the perceptions of families and health care providers on the amount of RUTF received, consumption and use practices, and their attitude towards a possible dose reduction.
2. Relapse rate measured as the proportion of children treated for SAM and declared cured who revert to SAM within 3 months of completing treatment, using anthropometric measurements including weight (kg), height (cm), and arm circumference (mm) taken using scales, height chart and tape measure at 3 months after treatment
3. Psychomotor development measured using the Psychomotor Development Index (PDI) at admission, discharge, and 6 months after treatment
4. Duration of the edema melting measured as the number of days taken for the lower limbs of SAM children to return to their normal volume using a tape measure at all study visits
5. Length of stay measured as the number of days between admission and discharge (with discharge occurring at PB≥12.5 cm and/or PT ≥-3 z-score and/or edema melt). The maximum length of stay is 12 weeks or 3 months
6. The cure rate measured as meeting the cure criteria according to admission category during two consecutive visits and no edema during two visits in two consecutive weeks measured using PT index (≥-1.5) or PB (≥125 mm) and edema at all study visits
7. The dropout rate measured as the proportion of children confirmed alive who missed two successive visits, at all study visits. The abandonment is confirmed once after the visit of the RECO which confirms that the child is alive despite his 2 absences during the weekly visits. Children who have been abandoned will be followed up to 3 months after the abandonment. For children who can be found, offer the caregivers a small snack at a single appointment 3 months after abandonment to take the anthropometric measurements.
8. Death rate measured as the proportion of children randomized to the study who died during the intervention at any time
9. Cost savings (average cost saved and cost saved per child treated) measured by comparing the cost of treatment for children in care and declared cured in the two groups using the direct costs of drugs and RUTF (purchase, transport, transport, and storage) to assess the cost for each child, the HR costs involved in the care, the non-medical costs (food and transport. beneficiaries), and indirect costs (loss of productivity) throughout the trial
10. Prevalence of stunting and being underweight measured using anthropometric measurements including weight (kg), height (cm), and arm circumference (mm) taken using scales, height chart, and tape measure at the end of the treatment.

Previous secondary outcome measures:
1. Acceptance of a reduced dose during SAM treatment by health care personnel and the community: this involves assessing the perceptions of families and health care providers on the amount of RUTF received, consumption and use practices and their attitude towards a possible dose reduction. Assessed using a qualitative approach by organizing discussion groups, in-depth interviews and direct observation using interview and focus group guides as well as observation

grids. This survey was conducted in November 2021
2. Relapse rate: the proportion of children treated for SAM and declared cured who revert to SAM within 3 months of completing treatment, assessed using anthropometric measurements including weight (kg), height (cm) and arm circumference (mm) taken using scales, height chart and tape measure
3. Psychomotor development: this sub-study aims to assess the proportion of children with psychomotor developmental delay (PDD) and to monitor their progress during treatment. Psychomotor developmental delay (PDD) refers to impairments in the acquisition of skills and competencies in the areas of language, cognitive, motor, and social interaction. PDD corresponds to a score of less than 70% in two of the four domains of Psychomotor Development (DPM) at admission, discharge, and 6 months after treatment. In this substudy, it is expected that the DPM of children with Psychomotor Development Delay (RDPM) will improve after treatment simply as a result of medical and nutritional intervention without any specific action on the DPM during treatment.

Completion date
30/08/2022

Eligibility

Key inclusion criteria
1. Children aged 6 to 59 months
2. Only one child per sibling included in the study
3. Severe acute malnutrition (weight-height index <-3 Z-score and/or mid-upper arm circumference <115 mm and/or bilateral edema (+: edema localized to the lower limbs; ++: edema localized to the lower and upper limbs)
4. Without medical complications
5. With conclusive appetite test
6. Living in the selected health zone
7. Consent to participate in the study (informed consent)
8. When there are several participants in the same sibling, only the first to be included in the study will be randomized. The others will automatically be included in the same group as the first one without being randomized and will not be taken into account in the analyses

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
968

Key exclusion criteria
1. Inconclusive appetite test
2. Siblings of SAM children: any SAM child whose brother or sister (same father, same mother) is already enrolled in the study. Be careful, he/she will have to receive the same dose as his/her brother or sister outside the study in order not to create a bias with different doses within the same family
3. Declared allergy to peanut and/or milk
4. Previously treated for SAM in the past 6 months, including readmissions after program dropout, relapses and medical transfers
5. Malformation or disability or chronic pathologies that can affect food intake, such as cleft palate, cerebral palsy, trisomy 2, sickle cell anemia

Date of first enrolment
19/08/2021

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
Congo, Democratic Republic

Study participating centre
Mudiba
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Solola (Grâce de l'Eternel)
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Tubondo 2
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Dubai
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Kashala Bonzola
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Nyongolo
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Lubilanji
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Dumarche
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Tudikolela
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
PMKO
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Lutulu
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Aéroport
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Tarmac 2
Mbujimayi
Congo, Democratic Republic
8010

Study participating centre
Tatu Muya
Mbujimayi
Congo, Democratic Republic
8010

Sponsor information

Organisation
Action Against Hunger

Funder(s)

Funder type
Government

Funder Name
Foreign, Commonwealth and Development Office

Alternative Name(s)
Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated and/or analyzed during the current study are/will be available on request from Dr Julien Ntaongo Alendi (j.ntaongo@gmail.com). The data that will be available will concern anthropometric measurements, patient care and psychomotor development. The data will be progressively available from December 2022 for an indefinite period. The data will be available to researchers (who want one or the other aspect of the research), actors in the field (for certain orientations of their programs), students for their dissertations or any other motivated use to the investigator. Out of respect for ethical principles, no data allowing the identification of patients will be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/05/2025	19/05/2025	Yes	No
Protocol file	version 6	05/01/2022	15/05/2023	No	No
Statistical Analysis Plan			15/05/2023	No	No