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# Effectiveness of improved diet for children with moderate acute malnutrition

**Submission date**
29/07/2013

**Recruitment status**
No longer recruiting

**Registration date**
02/08/2013

**Overall study status**
Completed

**Last Edited**
13/08/2025

**Condition category**
Nutritional, Metabolic, Endocrine

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

## Plain English summary of protocol

Background and study aims
Moderate acute child malnutrition (MAM) is a major global health problem, affecting about 36 million children worldwide. Children with moderate acute malnutrition are thin, and compared to a reference, do not weigh as much for their particular height as they should. As a result they have an increased risk of illness, reduced physical and mental development, and death. In emergencies or during recurrent food crisis children with MAM have traditionally been treated with fortified blended foods, such as Corn Soy Blends (CSB). It is now well recognized that CSB is inadequate for small children and products therefore need to be improved. Recently, improved CSBs (iCSBs) and lipid-based nutrient supplements (LNS) have been proposed as an alternative and are being tested. However, there is no consensus on the most suitable product and there is a need to develop and test new products. Twelve investigational food supplements will be developed, including six iCSBs and six LNS combining different soy qualities (dehulled soy, soy isolate) and different amounts of dried skimmed milk. This study aims to assess the effectiveness of a 3-month supplementation with these new products for the management in 6-23 months old children with MAM. Effectiveness will be assessed by determining their effects on body composition (i.e., how much fat and fat-free mass a childs body consists of), linear growth, physical activity, child development as well as other biological indicators of nutritional status, growth and infection. It will also be investigated whether children like the supplements.

Who can participate?
Children suffering from MAM

What does the study involve?
Each child is randomly allocated to receive one of the 12 supplements for a period of 3 months. During these 3 months the child should come to the health centre twice a month. After the 3 months supplementation period the child is asked to come to the centre once a month for a further 3 months period for follow-up. Mothers benefit from regular health, hygiene and nutrition education and children will undergo the following examinations:
1. Medical examination and treatment for any condition if necessary
2. Body measurements such as weight, height, mid-upper arm circumference, the length between knee and heel, and the thickness of the skin on the triceps and shoulder blade
3. Blood sampling. The blood is used for testing other indicators of nutritional status, growth

and infections
4. Assessment of the child's motor and language development
5. Assessment of physical activity using an accelerometer, a small electronic device attached to a belt worn around the hips of the children
6. Measurement of the thymus size, an organ which plays a role in defence against infections, using an ultrasound scanner
7. Body composition assessment
In addition, participants are asked questions about the type of food the child and the rest of the household usually eat, and if the children likes the supplementary foods. Of these examinations only the medical examinations and body measurements are done at every visit. Assessment of child development, physical activity and blood sampling are only done three times: at the start and after 3 and 6 months. Body composition is assessed only twice, at admission and after 3 months.

What are the possible benefits and risks of participating?
The supplements may improve management of MAM

Where is the study run from?
Province du Passoré (Burkina Faso)

When is the study starting and how long is it expected to run for?
August 2013 to September 2014

Who is funding the study?
Danish International Development Assistance (Denmark)

Who is the main contact?
Prof. Henrik Friis
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Henrik Friis

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# Additional identifiers

### Protocol serial number

N/A

# Study information

### Scientific Title
Effectiveness of improved diets for children with moderate acute malnutrition: a randomized controlled trial in Province du Passoré, Burkina Faso

### Acronym
TreatFOOD

### Study objectives
The research question is, which of twelve experimental food supplements, is most cost-effective in increasing lean body mass, and to improve functional outcomes, among 6-23 month-old children with moderate acute malnutrition.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Ethics Board in Burkina Faso, 01/08/2012, ref: 2012-8-059
2. Consultative approval from the Danish Ethics Board, 25/09/2012, Case No: 1208204 and Document No. 1046935

### Study design
Randomised nutrition intervention trial with a 2-by-2-by-3 factorial design

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Children with moderate acute malnutrition

### Interventions
Children will receive one of 12 newly developed food products at a quantity of 500 kcal per day for 12 weeks. No placebo or non-intervention group exists.

The 12 products include 6 improved CSBs and 6 lipid based nutrient supplements.The 12 products to be tested will all have the same micronutrient content, based on the WHO technical note on 'Supplementary foods for the management of moderate acute malnutrition in infants and children 659 months of age' (WHO, 2012), but will have different amounts of milk powder and either dehulled soy or soy isolate, a higher quality soy. That is the CSBs and LNS products will based either on dehulled soy or on soy isolate and containing either 0%, 20% or 50% of proteins provided by dry skimmed milk.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Absolute lean mass increment from baseline to 3 months measured using the deuterium dilution method

### Key secondary outcome(s))
1. Increase of WHZ to >-2 and linear growth, i.e. length and kneeheel length. Weight and knee-heel length measured at every bimonthly visit during the supplementation period and every monthly visit during the follow-up period. Height measured once a month.
2. Increase in mid upper arm circumference > 125 mm
3. Physical activity measured using an accelerometer, at 0, 3 and 6 months
4. Motor and language milestones development, measured using a adapted version of the Malawi Development Assessment Tool (MDAT) at 0, 3 and 6 months
5. Morbidity assessed during a clinical examination by a trained nurse and biological indicators measured in venous blood at every bimonthly visit during the supplementation period and every monthly visit during the follow-up period
6. Level of biological indicators of nutritional status, growth and immune function (haemoglobin, serum acute phase proteins, serum ferritin, essential fatty acids, insulin-like growth factor-1) measured in a venous blood sample taken from the childs arm at 0, 3 and 6 months
7. Thymus size measured using an ultrasound scanner at 0, 3 and 6 months
8. Acceptability of and adherence of products assessed using an acceptability questionnaire

### Completion date
01/09/2014

## Eligibility

### Key inclusion criteria
1. Weight-for-height z-score (WHZ) ≥ -3 and < -2 (based on the WHO growth standard) or Mid Upper Arm Circumference (MUAC) ≥115mm and < 125 mm
2. 6 to 23 months of age
3. Resident in the catchment area at the time of inclusion
4. Whose parents/guardians have signed (or thumb-printed whenever illiterate) the informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
6 months

### Upper age limit

23 months

### Sex
All

### Total final enrolment
1609

### Key exclusion criteria
1. Children with severe acute malnutrition defined as a WHZ < -3, and/or a MUAC <115 mm, and /or bilateral pitting oedema.
2. Children with medical complications requiring hospitalization
3. Children whose household plans to leave the catchment area in the next 6 months
4. Children with a hemoglobin concentration <4g/dl or with evidence of a decompensate anemia (e.g. dyspnea, tachycardia etc)
5. Children who have been treated for SAM or who have been hospitalized in the last 2 months
6. Children with known allergy to milk, peanut, corn soya blend (CSB) and/or ready to use therapeutic food (RUTF)
7. Children with a severe disability limiting the possibility of investigations
8. Children enrolled in any other nutritional program or part of any other study conducted in the area

### Date of first enrolment
19/08/2013

### Date of final enrolment
01/09/2014

## Locations

### Countries of recruitment
Burkina Faso

Denmark

### Study participating centre
**University of Copenhagen**
Frederiksberg
Denmark
1958

## Sponsor information

### Organisation
University of Copenhagen (Denmark)

**ROR**
https://ror.org/035b05819

# Funder(s)

**Funder type**
Charity

**Funder Name**
Doctors Without Borders (Médecins sans Frontieres) (UK)

**Funder Name**
Danish International Development Assistance (09-097 LIFE) (Denmark)

# Results and Publications

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**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 | observational study results | 01/02/2016 | | Yes | No |
| Results article | polyunsaturated fatty acid results | 13/07/2017 | | Yes | No |
| Results article | fat-free tissue accretion results | 11/09/2017 | | Yes | No |
| Results article | fat accumulation results | 01/09/2018 | 16/05/2019 | Yes | No |
| Results article | acceptability results | 01/04/2016 | 23/12/2019 | Yes | No |
| Results article | feeding behaviors results | 01/10/2017 | 23/12/2019 | Yes | No |
| Results article | hemoglobin, iron status, and inflammation results | 01/02/2018 | 23/12/2019 | Yes | No |
| Results article | inflammation results | 01/12/2016 | 23/12/2019 | Yes | No |
| Results article | physical activity results | 01/02/2017 | 23/12/2019 | Yes | No |
| Results article | admission criteria and body composition results | 06/08/2020 | 10/08/2020 | Yes | No |

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|---|---|---|---|---|---|
| Results article | child development results | 23/12/2020 | 29/12/2020 | Yes | No |
| Results article | | 08/05/2021 | 10/05/2021 | Yes | No |
| Results article | Serum cobalamin secondary analysis results | 09/03/2022 | 10/03/2022 | Yes | No |
| Results article | Liver function tests among children with moderate acute malnutrition: A secondary analysis of a randomized trial from Burkina Faso | 12/08/2025 | 13/08/2025 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |