

Effectiveness of improved diet for children with moderate acute malnutrition

Submission date 29/07/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/08/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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 child's 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 like 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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Study website

<http://www.treatfood.org>

Contact information

Type(s)

Scientific

Contact name

Prof Henrik Friis

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 6-59 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 be 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 measure

Absolute lean mass increment from baseline to 3 months measured using the deuterium dilution method

Secondary outcome measures

1. Increase of WHZ to >-2 and linear growth, i.e. length and kneeheel length. Weight and kneeheel 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 child's 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

Overall study start date

19/08/2013

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) ≥ 115 mm 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

Age group

Child

Lower age limit

6 Months

Upper age limit

23 Months

Sex

Both

Target number of participants

1608

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 < 4 g/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)

Sponsor details

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Sponsor type

University/education

Website

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ROR

<https://ror.org/035b05819>

Funder(s)

Funder type

Charity

Funder Name

Doctors Without Borders (Médecins sans Frontières) (UK)

Funder Name

Danish International Development Assistance (09-097 LIFE) (Denmark)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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
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