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Pilot research to test improved nutritional intervention and stimulation care for children with severe acute malnutrition in Tanzania

Submission date
08/03/2025

Recruitment status
No longer recruiting

Registration date
12/03/2025

Overall study status
Completed

Last Edited
12/03/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims.
Children with severe acute malnutrition (SAM) are at high risk of impaired development. Contributing causes include the inadequate intake of specific nutrients such as polyunsaturated fatty acids (PUFAs) and a lack of adequate stimulation. A ready-to-use therapeutic food (RUTF) has been developed with an essential fatty acid (EFA) content, which should improve the ratio between omega-6 (n-6) and omega-3 (n-3) EFA in the diet. This study tested the acceptability among children with SAM and their caregivers and assessed the EFA profile and variability before and after the interventions. This was compared with that of non-SAM children. The long-term plan is to conduct a larger study of a novel RUTF and psychosocial (PS) training intervention to determine their individual and potentially synergistic effects on cognitive development of children with SAM. The present development project will aid this by developing the content and delivery mode of the PS intervention; assessing acceptability of both RUTF and PS interventions; determining contextual factors influencing intervention delivery and uptake; determining variability in EFA and child development outcomes to aid sample size calculations; engaging with local health care staff managing SAM and providers of interventions to ensure that they are appropriate and locally owned; and, investigating the mechanisms that drive feasibility of implementation of the two interventions.

Who can participate?
Children aged 6-36 months old with SAM defined as mid-upper arm circumference (MUAC) <115 mm or weight-for-height (WHZ) z-score <-3 as per WHO growth standards or bilateral pitting oedema and caregivers giving consent ≥ 18 years

What does the study involve?
1. Acceptability of improved RUTF
Mothers with children recovering from SAM whose children asked to consume standard RUTF were asked to try the new RUTF.

2. Development of PS intervention
For the qualitative situational analysis, the study identified health and NGO managers from local

organisations to conduct semi-structured interviews. Interviews were also conducted with up to 20 caregivers of children within units for children with malnutrition.

3. Pilot of combined interventions
For the piloting of the interventions, children aged 6-36 months were recruited who were in treatment for SAM and the caregivers of these children.
Control children were to be frequency matched to the SAM children, based on age, sex and neighbourhood to assure similar socioeconomic level.

What are the possible benefits and risks of participating?
The benefits include involving a population of children with SAM during their critical period of brain development (6–36 months) who were provided with a locally created feasible intervention linked with local organizations.

Children with SAM were treated with RUTF and mothers were encouraged to provide psychosocial stimulation to improve nutritional and cognitive outcomes. No direct immediate risk was foreseen for those participating in the study.

Where is the study run from?
Mwanza, Tanzania.

Who is funding the study?
The study was funded by a joint global health trial development grant from the Department of Health and Social Care(DHSC), the Foreign, Commonwealth &Development Office (FCDO), the UK Medical Research Council (MRC) and Wellcome Trust

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MR/T003731/1

Study information

Scientific Title
BRIGHT-SAM: BRaIn development, Growth and HealTh in children with Severe Acute Malnutrition

Acronym
BRIGHT-SAM

Study objectives
Management of severe acute malnutrition can be improved through optimized nutritional treatment and integrated psychosocial support to improve child development and thus mitigate the consequences of climate change.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 06/02/2020, Medical Research Coordinating Commitee (National Institute for Medical Research, Box 9653, Dar es Salaam, 0000, Tanzania; +2552121400; ethics@nimr.or.tz), ref: NIMR/HQ/R.8a/Vol.IX/3340

2. approved 23/03/2020, Ethics Committee of The London School of Hygiene and Tropical Medicine (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)2076368636; study@lshtm.ac.uk), ref: Approval no. 17831

Study design
Interventional feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Treatment of children with severe acute malnutrition (SAM)

Interventions
This was a trial development interventional study conducted to inform the feasibility of providing therapeutic feeding with optimised essential fatty acids composition to children treated for severe acute malnutrition(SAM) in Tanzania alongside a psychosocial (PS) training programme to enable counselling with respect to child development for caregivers of children with SAM under the age of three years.

The study components included:
A) Acceptability of improved ready-to-use therapeutic food (RUTF)
B) Development of PS intervention
C) Piloting of interventions
D) Process evaluation.
A piloting procedure for assessing whether measures to assess the effectiveness of the package of care are appropriate for a larger randomized trial of intervention effects in the future.

Intervention Type
Supplement

Primary outcome(s)
Child development measured using the Malawi Development Assessment Tool (MDAT) at baseline and 8 weeks

Key secondary outcome(s))
1. Fatty acid status measured in whole blood using gas chromatography at baseline and 8 weeks
2. Growth measured using standard anthropometric techniques (mid-upper arm circumference, weight, weight for height/length z score) at baseline and 8 weeks
3. Caregiver stimulation and support assessed measured using the Family Care Indicators (FCI) questionnaire, structured observations of mother-child interactions (OMCI) and the Maternal Depression Scale (PHQ9) at baseline and 8 weeks

Completion date
03/12/2022

Eligibility

Key inclusion criteria
1. 6-36 months old
2. SAM defined as mid-upper arm circumference (MUAC) <115 mm or weight-for-height (WHZ) z-score <-3 as per WHO growth standards or bilateral pitting oedema
3. Age of caregiver giving consent ≥ 18 years

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
36 months

Sex
All

Total final enrolment
170

Key exclusion criteria
1. Allergy to peanuts or other ingredients of the RUTF
2. Any severe disorder preventing children from receiving interventions (e.g. not able to swallow RUTF)

Date of first enrolment
05/05/2020

Date of final enrolment
15/02/2022

Locations

Countries of recruitment
Tanzania

Study participating centre
National Institute for Medical Research
P.O.BOX 1462
Mwanza
Tanzania
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Sponsor information

Organisation
National Institute for Medical Research

ROR
https://ror.org/05fjs7w98

Funder(s)

Funder type
Not defined

Funder Name
Department of Health and Social Care

Alternative Name(s)
Department of Health & Social Care, DH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/02/2024	10/03/2025	Yes	No
Other publications	A qualitative interpretivist study used in-depth interviews to explore the 'subjective interpreted' reality of parents/caregivers of SAM children, and professionals providing SAM services	09/05/2024	10/03/2025	Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes