

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	<input type="checkbox"/> Prospectively registered
Registration date 12/03/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/03/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 Committee (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 \geq 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, Medical Research Committee and Advisory 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