ISRCTN86267988 https://doi.org/10.1186/ISRCTN86267988

Determining the efficacy of a specific nutritional intervention in Sri Lankan children with malnutrition

Submission date
11/02/2024

Recruitment status
No longer recruiting

Registration date
28/02/2024

Overall study status
Completed

Last Edited
11/03/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study focuses on children aged 6 to 59 months who are experiencing weight-for-height scores between -2 standard deviations (SD) and -3 SD, indicating they may be undernourished. The main goal is to see how many of these children can improve to a healthier weight and height range within 6 months. The study will also look at other factors like changes in weight, height, and various scores related to nutrition and health, such as weight/age, height/age, and weight /height ratios. Additionally, it will see if there are improvements in dietary diversity and haemoglobin levels, which can indicate overall health.

Who can participate?
Children aged 6 to 59 months who are malnourished

What does the study involve?
To do this, The study will compare two groups of children: one receiving standard care, which includes food assistance and monthly educational sessions on topics like breastfeeding and child development, and the other group receiving the same standard care plus additional support. This extra support includes a food basket every two weeks, a recipe booklet, and cooking demonstrations to help parents prepare nutritious meals at home.
The hope is that by providing these additional resources, the nutritional status of the children in the experimental group will improve and increase their chances of reaching a healthier weight and height. Overall, the study aims to understand how different interventions can impact child nutrition and health outcomes.

What are the possible benefits and risks of participating?
Benefits: There were two groups in the study. One group (experiment) received a food pack, cooking demonstration, and recipe booklet during the study, while the other group (control) received the same for six months after the study ended. Participating in this study helped the parents to learn more about nutrition.
Risks: The study involved minimal risks, such as slight fatigue during assessments and interviews. To make the finger prick test for hemoglobin less painful for children, distractions like

breastfeeding or playing with toys were used, along with local anesthetic creams.
After completion of the study, all children continued to receive standard care. The standard measurements proposed in the study for assessing infant and child nutrition are safe and widely used worldwide.

Where is the study run from?
Sri Lanka College of Paediatricians, Borella (Sri Lanka)

When is the study starting and how long is it expected to run for?
September 2022 to October 2023

Who is funding the study?
Government of France

Who is the main contact?
Guwani Liyanage, Professor in Paediatrics, guwani@sjp.ac.lk

Contact information

Type(s)
Scientific, Principal investigator

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Public

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Additional identifiers

Protocol serial number
FLA-2023-01

Study information

Scientific Title
Prospective randomized two-arm controlled study to determine the efficacy of a specific intervention to improve growth parameters of children with moderate acute malnutrition in four MOH areas in Nuwara Eliya district

Acronym
ENMAM

Study objectives
Additional in-kind food assistance and empowering parents on meal preparation would more effectively improve the growth parameters than the standard care provided at the primary care level for children under 5 years with moderate acute malnutrition

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2023, Ethics Review Committee (Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda, 10250, Sri Lanka; +94 (0)112758588; erc.fms@sjp.ac.lk), ref: ERC 02 /23

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Prevention of malnutrition in children

Interventions
There are 13 Medical Officer of Health (MOH) areas in the Nuwara Eliya district, categorized as predominantly rural, estate, urban, or mixed (rural/estate). One MOH area was randomly selected from each category. All children with undernutrition are registered with respective MOHs. They are routinely followed up every month at MOH clinics. Eligible children were listed from the register and identified the PHM area they belong to. Each PHM area was randomly assigned to either the intervention or control using a computer-generated random sequence

(MS Excel, Microsoft Corporation). One PHM area was considered as a cluster, totalling 102 eligible PHM areas. One PHM area was assigned to one nutritional intervention to reduce the likelihood of contamination between study arms through the sharing of the resources. Group assignments were not accessible to either participants or the investigators and were placed in sequentially numbered sealed envelopes before breaking the seal to reveal the assigned group.

The control group received standard care (two packs of ready-to-eat, corn-soya blend (Thriposha) as part of existing government safety net programs, and routine health promotion educational sessions every month. Educational sessions were carried out by the public health nurse and the midwives of each medical officer of the health office on breastfeeding, IYCF practices, food health and safety, sanitation, immunization, supplementary programmes and child development.

In addition to the above-mentioned standard care, the experimental group received a food ration (a food basket) every two weeks and an easy-to-prepare one-pot meal recipe booklet and cooking demonstrations using visual aids by the trained study team. The recipe booklet and the composition of the food basket were designed by a team of experts that included paediatricians, community physicians and nutrition physicians. The food basket was suitable for other settings and contained food items available in the local markets. It contained a dry ration worth 4000 LKR (cereals, legumes, dry sprats, coconut, coconut oil, soya meat, eggs and pasteurized milk for children over 2 years). The food basket was intended to supplement the child's diet and not to provide all of the required nutritional needs. The parents were given a message saying "This food basket is for you to supplement your child's diet and try not to share among others at home". The intervention will continue for 6 months.

Intervention Type
Mixed

Primary outcome(s)
The percentage of children improving to normal weight/height range (above -2 SD) calculated using weight and height, via the WHO Anthro Survey Analyser at baseline and the end of 6 months

Key secondary outcome(s)
1. Weight measured using an electronic scale at baseline and the end of 6 months
2. Height measured using length board/stadiometer at baseline and the end of 6 months
3. Weight for age Z score (WAZ) calculated using WHO Anthro Survey Analyser at baseline and the end of 6 months
4. Height/age Z score (HAZ) calculated using WHO Anthro Survey Analyser at baseline and the end of 6 months
5. Weight/height Z score (WHZ) calculated using WHO Anthro Survey Analyser at baseline and the end of 6 months
6. Mid-upper arm circumference Z score (MUACZ) measured using a standard MUAC tape at baseline and the end of 6 months
7. Haemoglobin levels using finger prick method with HaemCue machines at baseline and the end of 6 months
8. Diet quality measured using the Dietary Diversity Score (DDS) at baseline and the end of 6 months

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Aged 6 to 59 months
2. Weight for height Z scores between <-2SD to -3SD

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
All

Key exclusion criteria
1. Significant chronic illnesses such as chronic renal failure, chronic liver failure, congenital heart disease
2. Significant cardiovascular compromise, immunodeficiency, and neurological problems that affect nutrition

Date of first enrolment
27/03/2023

Date of final enrolment
22/04/2023

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Nuwara Eliya, Ragala
Nuwara Eliya
Kotagala, Lindula
Sri Lanka
22200

Sponsor information

Organisation
World Food Programme

ROR
https://ror.org/04kx2vh28

Funder(s)

Funder type
Government

Funder Name
Government of France

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study are available upon request from Guwani Liyanage, Professor in Paediatrics, guwani@sjp.ac.lk.
The type of data that will be shared: All of the individual participant data collected during the trial.
Timing for availability: Beginning 3 months and ending 36 months following article publication.
Whether consent from participants was required and obtained: Informed written consent from participants was required and obtained.
Comments on data anonymization: Data will be shared after de-identification.
Any ethical or legal restrictions: No restrictions. Ethical and administrative clearance was obtained.
Any additional comments: Study protocol will also be shared on a reasonable request.

IPD sharing plan summary
Available on request