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Somaliland Effectiveness Trial of iCCM Plus

Submission date
09/08/2023

Recruitment status
No longer recruiting

Registration date
03/10/2023

Overall study status
Completed

Last Edited
20/11/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Acute childhood malnutrition is a common condition in low-income countries that can result in impaired development, increased morbidity, and elevated mortality. Ensuring effective treatment for acute malnutrition in the most affected areas is challenging due to the low capacity of health systems.

Who can participate?
Children aged 6-59 months old will be invited to participate in the study if they live within the villages that are to be included.

What does the study involve?
The study will compare village-level treatment of acute malnutrition with treatment at a health centre. The village-level treatment will be delivered by a Family Health Worker, who is a volunteer who lives in the village and receives a small salary. The treatment will consist of giving deworming and antibiotic medicines, as well as a special therapeutic food that is widely used in malnutrition treatment programmes. Children in the control group will have to go to a nearby health centre to get this treatment, which is what everyone has to do at the moment.

The parent/carer of all the children will be asked to answer a questionnaire and the weight, height, and mid-upper arm circumference of the child will be measured. If children become malnourished during the trial they will be followed up by the study arm to see what happens to them.

What are the possible benefits and risks of participating?
There might be several benefits for participants. These include improved access to treatment, early detection of malnutrition, empowerment of community health workers, potential cost savings, increased community engagement, valuable research contribution, and the possibility of scaling up the intervention for a broader impact. The risks of the study are that people will be asked to give up their time to answer questions and have their children measured. Being weighed and measured may cause some temporary distress for the child.

Where is the study run from?
University College London, in partnership with Save the Children and the Somaliland Ministry of Health and Development

When is the study starting and how long is it expected to run for?
March 2022 to March 2025

Who is funding the study?
The Innocent Foundation (UK)

Who is the main contact?
Dr Andrew Seal, a.seal@ucl.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Somaliland Effectiveness Trial of iCCM Plus for the Treatment of Childhood Acute Malnutrition

Acronym
SETiPlus

Study objectives
Integration of a simplified, combined, approach for the treatment of acute malnutrition into an integrated community case management platform (iCCM+) leads to greater access to effective acute malnutrition treatment compared to facility-based treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 20/10/2023, UCL Research Ethics Committee (University College London, London, WC1E 6BT, United Kingdom; +44 (0) 20 7679 2000; ethics@ucl.ac.uk), ref: 4684/004

2. approved 12/08/2023, The Ministry of Health Development (Road Number 1 , Hargeisa, Somaliland, None available, Somalia; +252 63 4466061; herrgeye@gmail.com), ref: 2/1048/2023

Study design
Non-blinded prospective longitudinal cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)

Diagnostic, Prevention, Treatment

Health condition(s) or problem(s) studied
Acute childhood malnutrition (wasting and/or nutritional oedema)

Interventions
This is a non-blinded, prospective, longitudinal, cluster-randomized, controlled trial, using villages served by a single Family Health Worker (FHW; Community Health Worker) as the unit of randomisation.

The Trial Treatment Package (iCCM+) will be the provision of treatment for uncomplicated acute malnutrition, in children 6 months to 5 years, by FHW at the village level. The treatment will consist of the provision of ready-to-use therapeutic food (RUTF) and presumptive treatment with amoxicillin and albendazole.

The iCCM+ treatment package will be compared to the Current Treatment Package (iCCM) in which acute malnutrition is diagnosed by FHW but all cases are referred to a health facility for treatment. Diagnosis and treatment of pneumonia, malaria, and diarrhoea, and detection of danger signs followed by referral to a health facility, will be done in both study arms according to the current national (Somaliland) iCCM protocols.

Study participants will be allocated to one of the study arms according to the village (cluster) that they live in. Thirty clusters will be randomly allocated to the two study arms to give 15 clusters in each arm. In each arm, a cohort of children will be enrolled and followed longitudinally, with data collection conducted at baseline and after 12 months to determine the coverage of acute malnutrition treatment. Children that develop acute malnutrition and are identified by the FHW during the trial will be identified and followed until their status is: completed treatment and discharged (recovered); died; defaulted; non-progressed; non-recovered; or transferred to a treatment site outside the trial area.

Each study cluster will be comprised of a village (Somali: tuulo) in which an FHW has previously been appointed and is currently providing iCCM services. A tuulo may be comprised of a number of bootos or individual compounds, and extend over quite a large area. It is estimated that the average tuulo area ranges from 20-50 km. Forty tuulo have been found to lie within the study area and: have an active FHW who is employed by the MOHD and supported by Save the Children; lie >3 km and < 15km from an SC-supported referral facility; and use a SC facility as the main referral site for the FHW. One of these tuulo has been utilised in a recent prototype study to develop the operating model and test the feasibility of data collection. This tuulo will therefore be excluded from the study randomisation process.

Thirty tuulos will be randomly selected from the remaining eligible tuulos using random numbers generated in Excel. Following this stage, the 30 eligible tuulo will be randomly allocated, with 15 allocated to the control (iCCM) group and 15 allocated to the iCCM+ intervention group. Prior to the randomisation process, village-level approval for the study will be sought from the MOHD, local administrative authorities, and community representatives in each village. Village-level representatives will be consulted about the randomisation process. Randomisation will be done by listing all the villages in order of their catchment health facility and supervisor, then assigning each village a unique ID number. A random number, either 0 for control or 1 for intervention, will be assigned to the first tuulo in the list by generating a random number using an Excel RANDBETWEEN function. The rest of the tuulos will then be assigned to a study arm group by choosing alternating members from the list.

Intervention Type
Other

Primary outcome(s)
1. Treatment coverage for moderate acute malnutrition (diagnosed using mid-upper arm circumference (MUAC)), defined as being currently enrolled in a village-level or facility treatment programme, measured using study records on the day of the data collection
2. Treatment coverage for severe acute malnutrition (diagnosed using MUAC and/or nutritional oedema), defined as being currently enrolled in a village-level or facility treatment programme, measured using study records on the day of the data collection

Key secondary outcome(s))
1. Number of cases of acute malnutrition diagnosed by FHW measured using health worker record books over the study period
2. Recovery (Number of cases successfully discharged by the FHW or health facility as recovered, divided by total discharges multiplied by 100) measured using household follow-up interviews throughout the trial
3. Non-recovery proportion number of non-responses and non-progressions, divided by total discharges multiplied by 100) measured using household follow-up interviews throughout the trial
4. Default proportion (Number of defaulters divided by total discharges multiplied by 100) measured using household follow-up interviews throughout the trial
5. Relapse rate (proportion of cured children who become malnourished within 6 months of discharge) measured using household follow-up interviews throughout the trial
6. Death rate (Number of beneficiaries who died whilst registered in the programme, divided by total discharges multiplied by 100) measured using household follow-up interviews throughout the trial
7. Average length of stay in a treatment programme (days) measured using household follow-up interviews throughout the trial. Length of stay is the number of days elapsed between admission and discharge. Average Length of Stay = Sum of Individual Length of stay (recovered beneficiaries) in days / Number of recovered beneficiaries.
8. Average gain in MUAC (mm/week) measured using household follow-up interviews throughout the trial
9. Cost per child treated (admitted) measured using study and programme implementation cost records at the end of the study
10. Cost per child cured/recovered measured using study and programme implementation cost records at the end of the study
11. Prevalence of GAM at baseline and endline measured during baseline and endline surveys
12. Number of diagnoses and diagnostic rate (diagnoses per 1,000 children/month) for each condition (ARI, malaria, diarrhoea, and acute malnutrition) measured using health worker record books over the study period

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. Children aged 6-59 months
2. Living in households within the participating clusters (villages)

Participant type(s)
Patient, Population

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0.6 months

Upper age limit
59 months

Sex
All

Key exclusion criteria
1. Children that are absent from their households during data collection
2. Children that are in hospital for a reason other than malnutrition
3. Children that cannot be measured due to an impairment

Date of first enrolment
15/10/2023

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
Somalia

Study participating centre
Gabiley District
Hargeisa, Somaliland
Somalia
Not available

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research organisation

Funder Name
Fundación Inocente, Inocente

Alternative Name(s)
INNOCENT, INNOCENT FOUNDATION, Inocente Inocente Foundation, Fundación Inocente Inocente, La Fundación Inocente, Inocente, FII

Funding Body Type
Private sector organisation

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

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the study will be stored in a publicly available repository. We will use the UCL Research Data Repository at: https://rdr.ucl.ac.uk/

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes