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Effect of Ready to Use Foods (RUF) on feeding, caregiving and behaviour characteristics of 6 - 24 months old malnourished Pakistani children

Submission date
07/02/2020

Recruitment status
Suspended

Registration date
17/02/2020

Overall study status
Completed

Last Edited
12/05/2020

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
Undernutrition continues to be a major public health problem in poorer countries where it may be a partial cause of nearly half of all young child deaths. The less severe form of acute malnutrition (MAM) affects around 1 in 10 children under 5 under-five in Southern Asia and Africa and in some countries this is treated with a special high energy ready to use food (RUSF). Researchers have developed a questionnaire (International Complementary Feeding and Eating Tool, ICFET) which helps assess how children aged under two years eat: how much appetite they have for food and the extent to which they refuse it. They plan to use the ICFET in a controlled trial to assess the extent to which RUSF may improve or spoil appetite in children with MAM.

Who can participate?
Children with MAM aged between 6 and 24 months who have not been treated for MAM previously

What does the study involve?
The researchers will give RUSF to 60 children aged between 6 and 24 months with newly diagnosed MAM in 3 health units in Lahore district and compare these to 60 children in 3 other health units who will receive only multivitamin and mineral supplements. They will be identified and referred by community lady health workers. The researchers will follow these children up after one month of treatment and another month after treatment has stopped. This will allow them to find out whether appetite and intake of family foods is reduced when RUSF is given, how often children recover from MAM without any treatment and whether children who are short rather than thin show different growth and appetite patterns. In two basic health units, the researcher (Amara Khan) will also provide targeted counselling based on the ICFET at the end of the follow-up period, in order to assess how practical and time-consuming this is.

What are the possible benefits and risks of participating?
In both groups the children will be receiving vitamin and mineral supplementation, this will be an

incentive to participate. Some measurements might be of discomfort for children, but all measurements will be taken with the help of mothers, so the children remain comfortable and children will be given a toy to keep them entertained during data collection.

Where is the study run from?
This study will be carried out in the outskirts of Lahore the capital of Punjab Province of Pakistan, The study will take place in 4 Basic Health Unit (BHU) and 2 Rural Health Centres (RHCs) where the current nutrition programme is being provided by the Department of Health Punjab.

When is the study starting and how long is it expected to run for?
April 2019 to October 2020

Who is funding the study?
This study is part of a PhD project under the University of Glasgow who will be providing some funding as well as the local preventive services (IRMNCH) who run the basic health units

Who is the main contact?
1. Amara Khan
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2. Prof. Charlotte Wright
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3. Dr Ada Garcia
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
200190018

Study information

Scientific Title
Effect of Ready to Use Foods (RUF) on feeding, caregiving and behaviour characteristics of 6- 24 months old malnourished Pakistani children: a cluster randomised trial

Acronym
ERUF

Study objectives
1. Are appetite for and intake of family foods reduced when RUSF is given?
2. How common is spontaneous recovery from MAM?
3. Are there subgroups of MAM children who respond less well to RUSF and is the eating behaviour and intake of other foods worsened by treatment with RUSF in these children?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/10/2019, College of Medical, Veterinary & Life Sciences Ethics Committee for Non-Clinical Research Involving Human Participants (Room B313, Sir Graeme Davies Building, University Avenue, Glasgow, G12 8TA, UK; Tel: +44 (0)141 330 5206; Email: mvls-ethics-admin@glasgow.ac.uk)

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, can be obtained from Amara Khan (1001653k@student.gla.ac.uk)

Health condition(s) or problem(s) studied
Moderate malnutrition among children aged 6 to 24 months

Interventions
A cluster RCT will be conducted to assess the impact of RUSF on eating and feeding behaviours of malnourished children. The participants will be newly identified MAM (Weight -3 to -2 SD and /or mid upper arm circumference (MUAC) 11.5 - 12.5 cm) cases. The unit of randomisation will be a PHC.

Six selected PHCs will be labelled as A to F and these PHCs will be randomized to provide RUSF or micronutrient supplements (MMS) with no ready to use foods. Active community screening and referral by LHWs will help to complete the recruitment and follow up within 4 months' time.

In two clusters (A & E), the researcher (AK) will also provide targeted counselling based on the ICFET at the end of the follow-up period, in order to assess the feasibility and time taken to do this.

This study involves one interview session for mothers/caregivers and child's anthropometric measurement at the time of recruitment, and provision of RUSF or MMS one sachet/day. Mothers of children recruited at PHCs A, & E will also be provided with targeted nutrition counselling based on their responses to ICFET. After 1 month one follow-up visit will be required with repeating the anthropometry, same interview questionnaire, and follow-up with the counselling group to record the behavioural changes. Before starting the RCT standardization of anthropometric measurement will be done.

Sample size
Given the time frame and incident of malnutrition it will be realistic to recruit a sample size of 120 children. With allowance for loss to follow up (10%) and an ICC of 0.03 this gives 80% power at p=0.05 to detect a standardised difference of >0.66. Using existing cross-sectional ICFET data from Pakistan and a small pilot longitudinal study from Kenya, this suggests we would give sufficient ample power to detect a difference of 0.5 points between intervention and controls in avidity or food refusal and marginal power to detect a difference of 0.5 points for force-feeding.

Intervention Type
Supplement

Primary outcome measure
Food avidity and refusal scores and family food intake as measured by the ICFET interview at 1 month after the start of RUSF/MMS

Secondary outcome measures
1. % of children in the control group who recover from MAM during follow up, defined as weight above -2SD and MUAC >12.5 cm, assessed via weight and height measured after 1 month
2. Mean change in weight z score, avidity and refusal scores in the intervention group at 1 and 2 months follow up for stunted compared to non-stunted children and for high bony frame compared to low bony frame

Overall study start date
01/04/2019

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. All 6-24-month-old moderately malnourished children living around the catchment population of selected health facilities
2. Children who have not received any treatment before for malnutrition and are otherwise not sick

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
24 Months

Sex
Both

Target number of participants
There are going to be two clusters and 60 participants will be recruited in each cluster

Key exclusion criteria
1. Children more than 24 months or younger than 6 months
2. Moderately malnourished children of 6 to 24 months of age who are sick or on medical treatment
3. Those moderately malnourished children who have been treated for severe acute malnutrition previously

Date of first enrolment
06/01/2020

Date of final enrolment
30/10/2020

Locations

Countries of recruitment
Pakistan

Study participating centre
BHU Ali Raza Abad
Ali Raza Abad Raiwind Road
Lahore
Pakistan
3110000

Study participating centre
BHU Arrian
Jia Bagga Rd, Kot Araian, Lahore, Punja
Lahore
Pakistan
3110000

Study participating centre
RHC Raiwind
Railway Colony Raiwind
Lahore (Kasur)
Pakistan
3110000

Study participating centre
RHC Chong
Manowal, Lahore, Punjab
Lahore
Pakistan
3110000

Study participating centre

BHU Maraka
Maraka, Lahore Cantt
Lahore
Pakistan
3110000

Study participating centre
BHU Sham kay Bhattian
Sham Kay Bhattian, Raiwind
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Sponsor information

Organisation
University of Glasgow

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Sponsor type
University/education

Website
http://www.gla.ac.uk/

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Research findings will be disseminated with all stakeholders working on malnutrition in Pakistan including health department. Copies of the research thesis will also be made available to the ethics committees in Pakistan. Research findings will be published in peered review journals and presented at national and international conferences.

Intention to publish date
01/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Amara Khan (1001653k@student.gla.ac.uk) and Prof. Charlotte Wright (charlotte.wright@glasgow.ac.uk).

IPD sharing plan summary
Available on request