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Ready to Use Supplementary Foods (RUSF) to prevent stunting among children under five years in Kurram Agency

Submission date
22/11/2017

Recruitment status
No longer recruiting

Registration date
11/12/2017

Overall study status
Completed

Last Edited
31/03/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The Federally Administered Tribal Areas (FATA) of Pakistan, represent the worst nutrition situations at national level due to the series of natural disasters and the challenge of militancy and responding military operations limiting access and development of livelihood/economic activities and agriculture. The National Nutrition Survey (NNS) 2011 reflects 58% stunting rates in children under 5 years of age in FATA. This study will review and test Ready to Use Supplementary Foods (RUSF) in a cohort of pregnant (group 1), lactating women (group 2), children aged 6-23 months (group 3) and 24-59 months (group 4) and the subsequent impact on stunting prevention in children aged under 5 years. The aim of this study is to evaluate the effectiveness of selected nutrition-specific interventions improving childhood length for age scores.

Who can participate?
Group 1: Pregnant woman
Group 2: Lactating women
Group 3: Children aged 6-23 months
Group 4: Children aged 24-59 months

What does the study involve?
Participants are allocated to groups selected from 12 health facilities catchment areas. Groups that have a community healthcare worker receive the treatment while groups in the area without a community healthcare worker receive their standard level of care. Those in group 1 and 2 receive a certain type of RUSF. This is given in daily rations throughout pregnancy and the first six months of breastfeeding. Those in the group 3 receive RUSF in daily rations for 18 months. Those in group 4 receive a RUSF daily for 36 months. Data is collected at baseline and followed up with bodymeasurements conducted monthly from each study participant. Participants are followed up for their length for age scores at the end of the project i.e. 3 years. They are also assessed for nutritional intake during pregnancy, maternal weight gain, exclusive breast feeding up-to 6 months, and birth weight.

What are the possible benefits and risks of participating?
Participants may benefit through the consumption of food supplements. There are no risks involved while taking part in this research study except for minor bruise and discomfort during blood sampling.

Where is the study run from?
Agency Surgeon Office (Kurram Pakistan)

When is the study starting and how long is it expected to run for?
July 2017 to December 2020

Who is funding the study?
United Nations World Food Programme (WFP)

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A community-based cluster controlled trial to evaluate the effectiveness of Ready to Use Supplementary Foods (RUSF) and proportional contribution of multi-sectoral interventions in the prevention of stunting among children under five years in Kurram Agency, Pakistan

Study objectives
Selected nutrition-specific interventions implemented during early pregnancy, lactation and in children 6-59 months of age in different bundles will cause a shift of 0.25 in mean LAZ score among children in intervention clusters compared to those in control clusters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board, Khyber Medical University, 28/08/2017, ref: DIR/KMU-EB/SP/000427

Study design
Interventional cluster controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Stunting prevention in children 6-59 months of age

Interventions
The allocation of participants into the four groups in the intervention and control clusters is non-randomized. Clusters (each ~150 households) with a Lady Health Worker (community health workers) are assigned to intervention arm while clusters with no Lady Health Worker are assigned to the control arm. In each of the cluster (both in intervention and control arm) four groups are recruited as:
Group 1: Pregnant women between the ages of 15-49 years
Group 2: Lactating women and group 3 & 4: Children age 6-23 months and 24-59 months.

From each of the cluster an average number of 22 pregnant women, 22 lactating women, 23 6-23 months children and 23 24-59 months are enrolled for the study. Data is collected at baseline and followed up with anthropometric measurements conducted monthly from each study participant along with yearly blood and fecal sample from a sub-group of study participants.

The different treatments include:
Lipid-based Nutrient Supplements (LNS) for Pregnant and Lactating Women (Local name: Maamta): These Ready to Use Supplementary Foods (RUSF) are given to pregnant and lactating women in Group 1 and Group 2. Supplementation will start from conception/earliest confirmation of pregnancy while for lactating women during the first 6 months of lactation. Active ingredients include: Roasted chickpeas, roasted yellow lentils, roasted peanuts, soybean oil, palmolein oil, hydrogenated vegetable fat as stabilizer, skimmed milk powder, sugar, maltodextrin, vitamins & minerals, emulsifier and antioxidant. The daily ration: 75 g sachet (One sachet per day is recommended for maintenance of nutritional status), throughout pregnancy and first 6 months of lactation. Maamta is manufactured within a quality and food safety management environment in accordance with latest version of recognized international standards and best practices and/or guidelines.

Lipid Based Nutrient Supplements (LNS) for Children (Local name: Wawa-mum): These Ready to Use Supplementary Foods (RUSF) are given to children 6-23 months of age in Group 3 of the trial. The active ingredients include: Roasted chickpeas, vegetable oil, dry skimmed milk, sugar, vitamins & minerals, emulsifier and antioxidant. The daily ration is 50 g sachet, one sachet per day is recommended. The average duration of intervention is 18 months under stunting prevention depend on age of the child at the time of assistance, starting from 6 months to 23 months of child age. Wawa-mum is manufactured within a quality and food safety management environment in accordance with latest version of recognized international standards and best practices and/or guidelines.

Micro-Nutrient Powder (MNP) for Children (Local name: Vita-Mixe): These Ready to Use Supplementary Foods (RUSF) are given to children 24-59 months of age i.e. group 4 of the trial. Micro-nutrient powder is homogeneous, stable and dry packed in 1 g sachet. The daily ration is 1 gram sachet, one sachet per alternate day is recommended under stunting prevention (one sachet for two days).
The average duration of intervention is 36 months under stunting prevention depends on the age of the child at the time of assistance, starting from 24 to 59 months of child age. MNP is formulated and manufactured in accordance with latest version of recognized international standards and best practices and/or guidelines.

Intervention Type
Supplement

Primary outcome(s)
Current primary outcome measures as of 30/12/2021:
1. Change in Length-for-Age Z scores (LAZ) is measured using the height boards (SECA) at each month in the intervention vs control arms, compared to the baseline LAZ score against WHO 2006 growth standards. (Timeframe: Baseline, thereafter monthly till the end of the study (3 years))
2. Change in Weight-for-Age Z scores (WAZ) is measured using the digital weighing scales (SECA) at each month in intervention vs control arms, compared to the baseline WAZ score against WHO 2006 growth standards. (Timeframe: Baseline, thereafter monthly till the end of the study (3 years))

3. Change in Weight-for-Height Z scores (WHZ) is measured using the digital weighing scales (SECA) and height boards (SECA) at each month in intervention vs control arms, compared to the baseline WHZ score against WHO 2006 growth standards. (Timeframe: Baseline, thereafter monthly till the end of the study (3 years)
4. Change in Early Childhood Development scores is measured using the Caregiver-Reported Early Development Instrument (CREDI) in the intervention vs control arms. (Timeframe: 12 months and 24 months after delivery)

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1. Change in Length-for-Age Z scores (LAZ) is measured using the height boards (SECA) at each month in the intervention vs control arms, compared to the baseline LAZ score against WHO 2006 growth standards. (Timeframe: Baseline, thereafter monthly till the end of the study (3 years))
2. Change in Weight-for-Age Z scores (WAZ) is measured using the digital weighing scales (SECA) at each month in intervention vs control arms, compared to the baseline WAZ score against WHO 2006 growth standards. (Timeframe: Baseline, thereafter monthly till the end of the study (3 years))
3. Change in Weight-for-Height Z scores (WHZ) is measured using the digital weighing scales (SECA) and height boards (SECA) at each month in intervention vs control arms, compared to the baseline WHZ score against WHO 2006 growth standards. (Timeframe: Baseline, thereafter monthly till the end of the study (3 years)

Key secondary outcome(s))
1. Infant and Young Child Feeding (IYCF) indicators is measured using a questionnaire (WHO guideline based) at baseline and at the end of the study in the intervention vs control arm. (Timeframe: Baseline and at the end of the study)
2. Birth weight of live newborns is measured using digital weighing scales (SECA) at 24 hours of birth in the intervention vs control arm. (Timeframe: Within 24 hours of delivery)
3. Nutritional intake (energy and protein) measured using 24-hour dietary recall method (FAO guideline based) at baseline and at the end of the study. (Timeframe: Baseline and at the end of the study)
4. Maternal weight gain during pregnancy is measured using digital weighing scales (SECA) at baseline, thereafter monthly till delivery in the intervention vs control arm. (Timeframe: Baseline, thereafter monthly till delivery)
5. Hemoglobin, albumin and micro nutrients like iron, zinc, iodine and vitamins are measured using blood samples at baseline, thereafter yearly till the end of the study (3rd year end) in a subsample in the intervention vs control arm. (Timeframe: Baseline, thereafter yearly till the end of the study (3rd year end))

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Group 1:
1. Pregnant women between the ages of 15-49 years will be recruited in the first group.
2. Pregnant women will be invited in their first trimester (preferably 1st two months of pregnancy).

Group 2:
1. Lactating women will be recruited in this group.
2. Lactating women will be invited within the early days following delivery (preferably within 2 months of delivery).

Group 3 & 4:
1. Children age 6-23 months and 24-59 months will form group 3 and 4 respectively
2. In group 3 children with ages between 6-18 months will be invited for the trial
3. Similarly for group 4 children with ages between 24-48 months will be invited
4. Preferably these children will be recruited from the households from which pregnant and lactating women were invited

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 months

Upper age limit
49 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 30/12/2021:
1. Children with Severe Acute Malnutrition (SAM) or Moderate Acute Malnutrition (MAM) will be excluded and referred for treatment
2. Similar nutrition specific interventions currently being implemented in the selected cluster
3. Participants planning to move from the study area during the study timelines
4. Children with congenital malformations identified at the baseline or severe developmental impairment such as cerebral palsy and children for whom LNS is contraindicated (malabsorption /metabolic disorder) or who are unable to take LNS (e.g. cleft palate) will be excluded

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2. Similar nutrition specific interventions currently being implemented in the selected cluster
3. Participants planning to move from the study area during the study timelines

Date of first enrolment

18/12/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
Pakistan

Study participating centre
Agency Surgeon Office
Kurrum Agency of Federally Administered Tribal Areas of Pakistan
Parachinar
Pakistan
25000

Sponsor information

Organisation
Khyber Medical University

ROR
https://ror.org/00nv6q035

Funder(s)

Funder type
Charity

Funder Name
United Nations World Food Programme (WFP)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/09/2024	25/09/2024	Yes	No
Interim results article	Results for Wawa-mum supplement in children aged 6-23 months	27/07/2023	14/08/2023	Yes	No
Other publications	Cross-sectional study as part of the main study to estimate the burden and determinants of maternal undernutrition in a low-resource setting	26/01/2026	31/03/2026	Yes	No
Participant information sheet			05/01/2018	No	Yes