

# Effect of nutritional supplements in moderate underweight children

<b>Submission date</b> 24/11/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/05/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

It has been shown that high energy nutritional supplements are very effective in treating malnutrition in developing countries. They promote weight gain and increase in energy intake, improves lipid profile and micronutrient status. This study aims to determine the effect of high-energy, nutritional supplements on appetite, energy intake, lipid profile and micronutrient status of moderately malnourished children.

### Who can participate?

Children aged between 5-10 years with moderate malnutrition from the primary government schools and orphanages.

### What does the study involve?

After taking consents from schools, children are selected according to inclusion criteria. The information/ protocols of the study are discussed in detail with the parents/guardians and the children. Participating children are randomly allocated to one of two groups. Those in the first group receive the supplement. Those in the second group receive the placebo (a dummy supplement). Then the children are requested to take data on multiple pass 24 hours dietary recall for 3 consecutive days before trial, after trial and after 15 days of trial. On main trial day, fasting state blood samples are collected. Height, weight, biceps and triceps skin folds, head and mid-upper-arm circumference and waist to hip ratio of the child are measured. After marking the appetite questionnaire, they are provided with supplement/placebo and then with ad libitum buffet breakfast and ad libitum buffet lunch at specific time intervals. Appetite questionnaires are marked at 30, 60, 120, 150, 180 and 210 minutes after supplementation. On day 31st of trial the children are requested again to come to clinical trial room in fasted state and the procedure are repeated as day 1st of trial. From day 2-30, children are given these supplements/ placebo in their school for four weeks and will be asked to consume supplements/ placebo in addition to their usual diet. The children are asked to keep the empty sachet of the supplements/ placebo with them after eating, which are collected by the main researcher next day in order to check the compliance. Further, the parent/ carer are requested to attend a focus group regarding the appetite of their child once before the start of study and once at the end of the study.

What are the possible benefits and risks of participating?

There will be no major benefits or risk of participating. The parent/carer may benefit by finding out about their child's body measurements and receive information regarding their child's nutritional status before and after supplementation. The children may gain weight as well. As dietary counseling is a fundamental and effective part of the treatment of moderate malnutrition, the parent/ carer will get some counseling on the completion of the study. As for risks, there might be a small bruise on skin from where the blood is taken.

Where is the study run from?

The study is run from primary schools and orphanages of Peshawar district located in Hayatabad region of Khyber Pakhtunkhwa province in Pakistan.

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

October 2016 to April 2019

Who is funding the study?

Khyber Medical University Peshawar (Pakistan)

Who is the main contact?

Dr Sadia Fatima

drsadiafatima@gmail.com

Aqsa Zubair

aqsazbr2@gmail.com

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Sadia Fatima

### Contact details

Biochemistry Department  
Institute of Basic Medical Sciences  
Khyber Medical University  
PDA Building  
Block IV  
Phase 5  
Hayatabad  
Peshawar  
Pakistan  
25000

### Type(s)

Public

### Contact name

Ms Aqsa Zubair

### Contact details

Biochemistry Department  
Institute of Basic Medical Sciences  
Khyber Medical University  
PDA building  
Block IV  
Phase 5  
Hayatabad  
Peshawar  
Pakistan  
25000

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## **Study information**

### **Scientific Title**

Effect of nutritional supplements on energy intake, appetite, lipid profile and micronutrient status of moderate underweight children

### **Study objectives**

The supplementation will improve the energy intake and plasma micronutrient status of moderate underweight children. It will also have an effect on appetite and lipid profile of these children.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Research Ethics Committee of Institute of Basic Medical Sciences, Khyber Medical University Peshawar, 09/02/2017

### **Study design**

Single blind randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

## **Study type(s)**

Quality of life

## **Participant information sheet**

See additional files

## **Health condition(s) or problem(s) studied**

Moderate Malnutrition

## **Interventions**

The participants are randomly allocated to either receiving Ready to Use Supplementary Food (RUSF) (Acha Mum, provided by WFP) or to the Placebo group.

After taking consents from participants, data for multiple pass 24 hours dietary recalls are taken for 3 consecutive days (including a Sunday) before the actual trial day. On trial day the participants come to clinical trial room in KMU. The anthropometric measurements, data on appetite and the baseline blood samples in a fasted state is obtained in the morning. Then the supplement (Acha Mum by WFP) /placebo is provided. Further appetite questionnaire are marked at time interval of 30 and 60 minutes. An ad libitum buffet breakfast and ad libitum buffet lunch are presented at 90 and 240 minutes after provision of supplements respectively. Again at 120, 150, 180 and 210 minutes, appetite questionnaires are marked after the supplementation. Four researchers measure the energy intake during the breakfast and lunch to enhance the accuracy of the results. "Windiet® software" are used to calculate the total caloric intake.

The participants are given either the supplement or placebo for 30 days on daily basis by main researchers. On thirty-first day, anthropometric measurements and fasting blood samples are collected again from both groups and the procedure is repeated as explained above.

The total duration of the intervention is 4 weeks.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Weight is measured using a calibrated electronic scale at baseline and four weeks
2. Height is measured using with a portable stadiometer (Seca, Leicester, UK) using a stretch stature method at baseline and four weeks
3. Mid upper arm circumference is measured using the Shakir measuring tape on the "non dominant hand" at baseline and four weeks
4. Skin fold measurement is measured using a Holtain skin fold calliper (Holtain LTD, Crosswell, UK) to the nearest 0.2 mm at baseline and four weeks
5. Appetite is measured using a validated appetite questionnaire at baseline and four weeks
6. Head circumference is measured using the Lasso-o measuring tape at baseline and four weeks
7. Waist to hip ratio is measured using Lasso-o measuring tape at baseline and four weeks
8. Energy intake will be measured using Windiet® software
9. Lipid profile will be analyzed using Cobas C3 analyzer
10. Hemoglobin (Hb) levels are checked by using hematology analyzer
11. Status of Iron (Fe), zinc (Zn) and copper (Cu) in plasma are analyzed by atomic absorption

spectrometry (AAS)

12. Vitamin D and Calcium (Ca) levels are checked using a Cobas 8000 Modular Analyzer.

### **Secondary outcome measures**

1. Taste acceptability of supplements is measured using validated sensory evaluation questionnaires at baseline and four weeks
2. Perceived benefits of the supplements by parents/carers are measured using validated parent perception questionnaires at baseline and four weeks
3. Perceived side effects of the supplements by parents/carers measured using validated parent perception questionnaires at baseline and four weeks
4. Socio-economic status of participant will be categorized using validated demographic questionnaire

### **Overall study start date**

15/10/2016

### **Completion date**

30/04/2020

## **Eligibility**

### **Key inclusion criteria**

1. 5-10 years old
2. Underweight; moderate with -2 and -3 BMI Z score

### **Participant type(s)**

Other

### **Age group**

Child

### **Lower age limit**

5 Years

### **Upper age limit**

10 Years

### **Sex**

Both

### **Target number of participants**

60

### **Total final enrolment**

37

### **Key exclusion criteria**

1. Eating disorder
2. Allergic to supplements or any food allergy
3. Gastro-intestinal tract surgery

4. Gastrointestinal tract disorders
5. Previously taking any supplement regularly
6. Previously taking such medications that interacts with appetite

**Date of first enrolment**

20/12/2017

**Date of final enrolment**

03/05/2018

## **Locations**

**Countries of recruitment**

Pakistan

**Study participating centre**

**SOS village (Orphanage)**

Phase 5 Hayatabad Peshawar Pakistan

Peshawar

Pakistan

25000

**Study participating centre**

**Jica High School Peshawar Pakistan**

Hayatabad Peshawar Pakistan

Peshawar

Pakistan

25000

**Study participating centre**

**Government Primary Boys School**

Hayatabad Peshawar

Peshawar

Pakistan

25000

## **Sponsor information**

**Organisation**

Khyber Medical University Peshawar

**Sponsor details**

PDA building  
Block IV  
Phase 5  
Hayatabad  
Peshawar  
Pakistan  
25000  
+92 91 9217258  
doric@kmu.edu.pk

**Sponsor type**

University/education

**Website**

www.kmu.edu.pk

**ROR**

<https://ror.org/00nv6q035>

**Funder(s)****Funder type**

University/education

**Funder Name**

Khyber Medical University Peshawar

**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal. Additional documents (such as study protocol, statistical analysis plan) have been attached in PDF format.

**Intention to publish date**

30/04/2020

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from:

1. Aqsa Zubair: aqsazbr2@gmail.com
2. Fouzia Nawab: fouzia.nawab20@gmail.com
3. Meera Tanveer: meeratanveer1@hotmail.com
4. Akhlaq Ahmed: akhlaqahmedbiochem@gmail.com

Personal data of participants will be kept confidential. Each participant will be given a proper trial registration no. at start of the trial. Anthropometric measurements and blood analysis report of participants will be provided anonymously. Data will be available after completion of trial and it will be disposed of in 10 years as per university policy. All participants will be given a proper trial registration no. thus the data will be shared anonymously upon request from the researchers with journals and the working research groups. All the data collected during the research will be shared by presenting the results of the study in national and international conferences, meetings of nutrition society and then by publishing in peer reviewed journals. Consent from the guardians while assents from the children (participants) have been taken before the trial. Each participant will be given a proper trial registration no. at the beginning of trial. All the data will be linked anonymized. Personal information will be kept confidential. Ethical approval has been acquired from the research ethics committee of KMU and the ASRB. There are no ethical or legal restrictions.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			01/04/2019	No	Yes
<a href="#">Participant information sheet</a>			01/04/2019	No	Yes
<a href="#">Protocol file</a>			02/04/2019	No	No
<a href="#">Results article</a>	results	01/09/2018	22/10/2020	Yes	No
<a href="#">Results article</a>		03/03/2022	18/05/2022	Yes	No