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Effect of nutritional supplements in moderate underweight children

Submission date
24/11/2017

Recruitment status
No longer recruiting

Registration date
16/01/2018

Overall study status
Completed

Last Edited
18/05/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Participanting 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 procedureare 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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 os provided. Further appetite questionnaire aremarked 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 is 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 are repeated as explained above.

The total duration of the intervention is 4 weeks.

Intervention Type
Other

Primary outcome(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
10 years

Sex
All

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

ROR
https://ror.org/00nv6q035

Funder(s)

Funder type
University/education

Funder Name
Khyber Medical University Peshawar

Results and Publications

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?
Results article	results	01/09/2018	22/10/2020	Yes	No
Results article		03/03/2022	18/05/2022	Yes	No
Participant information sheet			01/04/2019	No	Yes
Participant information sheet			01/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			02/04/2019	No	No