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Impact of solid and liquid supplements on weight gain and appetite of children between 5 to 10 years

Submission date
10/02/2014

Recruitment status
No longer recruiting

Registration date
12/03/2014

Overall study status
Completed

Last Edited
13/09/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
It has been shown that solid ready-to-use food supplements are very effective in treating severe malnutrition in developing countries. They promote weight gain and increase in energy intake, which is higher when compared to changes caused by drinking medicinal high-energy milk-based drinks. However, their efficiency in treating moderate/mild malnutrition remains unknown. This study aims to compare the efficiency of high-energy, nutritional, solid, ready-to-eat supplements and liquid, milk-based supplements on the weight gain of children

Who can participate?
Children aged between 5-10 years with mild to moderate malnutrition from the participating primary schools.

What does the study involve?
School children will be randomly selected and then height and weight measurements will be taken. Children with mild to moderate malnutrition will be invited to participate in the study. The children will be randomly allocated to receive either solid ready-to-use food (Plumpy Nut) or liquid ready-to-use supplement (Fortini, Nutricia). Children will be given these supplements in their school for four weeks and will be asked to consume the supplements in addition to their usual diet. The children will be asked to keep the empty bottles/sachet of the supplements with them after drinking/eating, which will be collected by the main researcher next day in order to check the compliance. Any leftover in the bottle or sachet will be recorded. Height, weight, biceps and triceps skin folds and mid-upper-arm circumference of the child will be measured before the supplementation, two weeks after starting the supplementation and at the end of the supplementation. The child will fill in an appetite questionnaire before taking the first and the last supplement. Further, the parent/carer will be requested to attend a focus group regarding the appetite of their child once before the start of supplementation and once at the end of the study. At the end of the study, the children who were screened and did not meet the criteria for recruitment will be measured for height and weight.

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 childs body measurements and receive information regarding their childs nutritional status before and after supplementation. As dietary counselling is a fundamental and effective part of the treatment of mild to moderate malnutrition, the parent/carer will get some counselling on the completion of the study. There might be a risk of allergic reaction from the peanut butter used in the preparation of solid ready-to-use food. However, an allergic reaction will be rare as peanuts are part of the traditional diet of the participants and the eligible children and their parents will be asked to complete a health questionnaire.

Where is the study run from?
The study is run from primary schools of Abbottabad district located in the Hazara region of Khyber
Pakhtunkhwa province in Pakistan.

When is the study starting and how long is it expected to run for?
The study will start in March 2014 and is expected to be completed by August 2014.

Who is funding the study?
University of Glasgow, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
N/A

Study information

Scientific Title
Comparison of the effectiveness of solid ready-to-eat and a liquid ready-to-drink supplements for management of mild to moderate malnutrition in children from Pakistan: a randomized trial

Acronym
N/A

Study objectives
To compare the efficacy of solid ready to eat and liquid ready to drink supplements in promoting weight gain in mild to moderate malnourished children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The College of Medical Veterinary and Life Sciences, University of Glasgow, Research Ethics Committee, 14/05/2013
The Research Ethics Committee of Ayub Medical College Abbottabad 05/05/2013

Study design
Open labelled randomized trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mild and Moderate Malnutrition

Interventions
The participants are receiving either solid ready to use food (RTUF) (Plumpy Nut; Nutriset, Malaunay, France), or liquid ready to use supplement (LRUS) (Fortini, Strawberry, Nutricia).
The total duration of the intervention is 4 weeks.

A solid ready to use food (RTUF) and liquid ready to drink supplement (LRUS) will be provided to the children for four weeks. LRUS is a strawberry flavoured ready to drink sip feed available in 200 ml bottles with a flexible straw, and RTUF is individually packaged in airtight alu-foil sachet, looks like a thick paste and tastes like a slightly sweeter peanut butter. Daily the children in

RTUF group will be provided with one sachet of RTUF (92 g, 500 kcal/d), and the children in LRUS group will be provided with two bottles of LRUS (60 ml of LRUS will be removed daily from one of the two bottles in order to provide nearly 500 kcal/ day).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Weight measurement - The weight of the children will be measured wearing lightweight clothes without shoes with a calibrated electronic scale (Seca, Hamburg, Germany).
2. Height measurement - Height will be measured with a portable stadiometer (Seca, Leicester, UK) using a stretch stature method.
3. Mid upper arm circumference - Mid upper arm circumference will be measured with a flexible measuring tape on the left upper arm.
4. Skin fold measurement - Triceps, biceps and subscapular skin folds will be measured using Holtain skin fold calliper (Holtain LTD, Crosswell, UK) to the nearest 0.2 mm.
5. Appetite measures - Appetite sensations will be measured with validated appetite questionnaires (Flint et al., 2000).

All the primary outcomes will be measured before the supplementation (baseline), two weeks after initiation of the supplementation and at the end of the supplementation.

Key secondary outcome(s))
1. Taste acceptability of supplements
2. Perceived benefits of the supplements by parents/carers
3. Perceived side effects of the supplements by parents/carers

The secondary outcomes will be measured only before the supplementation (baseline) and at the end of supplementation.

Completion date
01/08/2014

Eligibility

Key inclusion criteria
1. Primary school children, aged between 5-10 years.
2. Mild to moderate malnutrition (Z-score between -2 and -1)
3. Healthy children
4. Not on any medication or on any nutritional supplements
5. Not following special diet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
10 years

Sex
All

Total final enrolment
68

Key exclusion criteria
1. History of eating disorder
2. History of gastrointestinal problems or surgery
3. History of food allergy
4. History of chronic illness
5. On any medication
6. Currently taking part in other research

Date of first enrolment
01/03/2014

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Pakistan

Study participating centre
Human Nutrition Section
Glasgow
United Kingdom
G31 2ER

Sponsor information

Organisation
University of Glasgow (UK)

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow (UK)

Alternative Name(s)
The University of Glasgow

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018	13/09/2019	Yes	No