

Does treatment for severe malnutrition make children who are short for their age overweight?

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Registration date 15/05/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/12/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A child that becomes severely thin due to malnutrition requires specialised treatment with medicines and a ready-to eat food (RUTF) that contains all of the necessary ingredients for recovery. Children can be identified for treatment using a tape that measures the circumference at the middle of the upper part of the arm. A potential problem is that if a child is very small for their age, the measurement of the arm might indicate that the child needs treatment when in fact the child has a small circumference because they are small for their age and may not be malnourished. The ready to eat food contains a lot of oil and it is a concern that giving this specialised food to small children who may not be malnourished might cause them to become overweight or develop too much fat as a result of treatment. Obesity is a risk factor for diseases in later life. The aim of this study is to identify whether giving treatment to children who have been identified using the measurement of the arm and are short for their age causes them to become overweight or have more fat than normal following treatment.

Who can participate?

The study recruited all children between the ages of 6 to 59 months who were identified as having severe malnutrition using measurement of the upper arm circumference and were admitted to a treatment programme for malnutrition.

What does the study involve?

The treatment given to the study participants was identical to the treatment given to any severely malnourished child being treated in Ministry of Health clinics in Malawi. The children were discharged as cured according to national guidelines for treatment. For study participants, additional measurements were made of the thickness of a fold of fat on the upper arm (the Triceps Skin Fold).

What are the possible benefits and risks of participating?

The treatment followed standard government guidelines and was no different to the treatment offered to children not enrolled in the study. No incentives were given for participation and there was no additional risk attached to participation in the study.

Where is the study run from?

The study participants were recruited from a total of five Ministry of Health clinics in Lilongwe District in Malawi: Nsaru, Nthondo, Nathenje, Chiwamba and Chilobwe.

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

The study enrolled children from March 2011 to March 2012.

Who is funding the study?

Family Health International (FHI 360) Food and Nutritional Technical Assistance. The cost of the Harpeneden Calipers was met by Valid International Ltd.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Protocol serial number

4001-08-1-01/4001-VALID- 00/Task Order 4.

Study information

Scientific Title

Does treatment for severe acute malnutrition for children aged 6-59 months, identified by Mid-Upper Arm Circumference and that are less than 65 cm or have low height for age and treated with Ready to Use Therapeutic Food cause the child to become overweight or obese following cure?

Study objectives

Height cut-offs are frequently used as a proxy for an age of 6 months to identify infants not eligible for treatment with ready-to-use therapeutic foods (RUTF) although this may exclude stunted children aged 6 months or older. This study examined whether stunted children aged 6

months or older with severe acute malnutrition (SAM), identified by mid-upper arm circumference (MUAC), and treated with RUTF were overweight or had excess adiposity following cure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Health Sciences Research Committee of Malawi, 30/11/2010, Protocol #817 MED/4/36c

Study design

Single-centre observational cross-sectional cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Overweight following treatment for severe acute malnutrition

Interventions

Children aged 6 to 59 months were enrolled in outpatient treatment for SAM if they had a MUAC less than 115 mm without medical complications irrespective of height on admission. 163 children were discharged as cured when a MUAC of 125 mm or greater was obtained for 2 consecutive clinic visits and the child was clinically well. MUAC, triceps skin fold (TSF) thickness and weight were measured at each visit and height was measured on admission and discharge.

Intervention Type

Other

Primary outcome(s)

Weight for height z-score on discharge

Key secondary outcome(s)

1. Triceps skin fold for age z-score on discharge
2. Arm fat index for age z-score on discharge
3. Weight for age z score on discharge

Completion date

18/12/2013

Eligibility

Key inclusion criteria

1. Aged 6 - 59 months
2. Mid upper arm circumference <11.5cm

3. Good appetite for ready-to-use therapeutic food
4. No medical complications requiring transfer to hospital
5. Consent from carer to participate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

59 months

Sex

All

Key exclusion criteria

1. Aged <6 months or >59 months
2. MUAC >11.5cm
3. Anorexia
4. Any medical complication requiring transfer to hospital
5. Refusal of consent

Date of first enrolment

01/03/2011

Date of final enrolment

29/03/2012

Locations**Countries of recruitment**

Malawi

Study participating centre

Lilongwe District

Malawi

N/A

Sponsor information

Organisation

Valid International

ROR

<https://ror.org/00sb6vz77>

Funder(s)**Funder type**

Not defined

Funder Name

FHI 360

Alternative Name(s)

Family Health International

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Valid International

Results and Publications**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://figshare.com/articles/MUAC_discharge_from_OTP_and_excess_adiposity/6200759). The study data is provided in Comma Separated Values (CSV) format. It is available now and will be available permanently to any user for any type of analysis. Participation in the study was by informed consent.

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	results	13/12/2018		Yes	No