# A comparison of diets to treat moderate childhood malnutrition

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
01/05/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/05/2008	Completed	Results
Last Edited	Condition category	Individual participant data
12/05/2008	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Mark Manary

#### Contact details

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# Additional identifiers

# Protocol serial number

2620-22-0-00-P-0089

# Study information

Scientific Title

Randomised controlled trial comparing the impacts of feeding with milk/peanut ready-to-use therapeutic food (RUTF), soy/peanut RUTF, and corn-soy blend (CSB) among children with moderate acute malnutrition in Malawi

#### Study objectives

12 - 60 month-old children with moderate acute malnutrition (weight-for-height z score [WHZ] greater than -3 and less than -2) whose caretakers are provided with supplements and counseling to feed the child with 75 kcal/kg/day of either milk/peanut ready-to-use therapeutic food (MP-RUTF) or soy/peanut ready-to-use therapeutic food (SP-RUTF) are more likely to recover from moderate acute malnutrition during an eight-week intervention than comparable children receiving isoenergetic rations of corn-soy blend (CSB); in addition among children receiving MP-RUTF or SP-RUTF, the recovery rate will not differ by more than 10%.

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics approval received from:

- 1. College of Medicine Research and Ethics Committee (Malawi) on the 17th July 2007 (ref: P.06 /07/564)
- 2. Washington University Human Studies Committee on the 18th July 2007 (ref: 07-0642)

#### Study design

Randomised, investigator blinded clinical effectiveness trial

# Primary study design

Interventional

# Study type(s)

**Treatment** 

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

Moderate malnutrition

#### **Interventions**

Feeding with one of three foods:

- 1. Ready-to-use milk/peanut fortified spread
- 2. Ready-to-use soy/peanut fortified spread
- 3. Corn soy blend

Children will receive isoenergetic amounts of one of the above three foods for up to eight weeks. The amount of food given is sufficient to provide 75 kcal/kg/d. The children will be followed biweekly, having weight, length, and mid-upper arm circumference measured; and the number of days of fever, cough and diarrhoea recorded from caretaker's report. Follow-up is for eight weeks.

# Intervention Type

Supplement

#### Phase

## Drug/device/biological/vaccine name(s)

**Nutritional supplements** 

#### Primary outcome(s)

Recovery, measured at the completion of the feeding period, usually eight weeks.

### Key secondary outcome(s))

- 1. Weight gain, measured after four weeks
- 2. Height gain, measured after four weeks
- 3. Mid-upper arm circumference gain, measured after four weeks

#### Completion date

30/06/2008

# Eligibility

## Key inclusion criteria

- 1. Children aged 12 60 months
- 2. Moderate acute malnutrition using the World Health Organization (WHO) criteria (WHZ greater than -3 and less than -2)
- 3. Reside within 7 km
- 4. Present to one of seven supplementary feeding sites in southern Malawi during the study recruitment period

#### Participant type(s)

Patient

# Healthy volunteers allowed

No

### Age group

Child

### Lower age limit

12 months

#### Upper age limit

60 months

#### Sex

All

#### Key exclusion criteria

- 1. Children who are not permanent residents in the vicinity of the local health centre (distance from home to health centre greater than 7 km)
- 2. Have severe chronic illnesses such as cerebral palsy

- 3. Have a history of peanut allergy or anaphylaxis resulting from any food
- 4. Receive other supplementary food from a government or charitable agency
- 5. Participating in another research study

#### Date of first enrolment

01/08/2007

#### Date of final enrolment

30/06/2008

# Locations

# Countries of recruitment

Malawi

United States of America

Study participating centre Department of Pediatrics

St. Louis, MO United States of America 63110

# **Sponsor information**

# Organisation

Academy for Educational Development (AED) (USA)

#### **ROR**

https://ror.org/034s15752

# Funder(s)

## Funder type

Research organisation

#### **Funder Name**

Academy for Educational Development (AED) (USA)

#### **Funder Name**

# **Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration