

# Stool frequency in Severe Acute Malnutrition

<b>Submission date</b> 29/11/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/10/2017	<b>Condition category</b> 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

Many young children in developing countries die because of malnutrition. If the children are admitted to hospital with severe acute malnutrition, the likelihood of dying is higher if they also suffer from diarrhea. It has been noticed that the mothers of many children might not always give an accurate report of the child's stool frequency and consistency. In order to provide good treatment an accurate report is very important. This study will compare what the mothers say about their children's defecation habits to what the healthcare workers are able to observe with the help of diapers. Our aim is to determine whether stool output as assessed by the maternal /carer recall method is same as when assessed using directly observed diapers in children with severe acute malnutrition.

### Who can participate?

All children admitted to the Nutritional Rehabilitation Center of the Queen Elisabeth Central Hospital in Blantyre, Malawi, will be asked to participate in this study.

### What does the study involve?

Children will be randomly allocated to either the control group, where the mothers will be asked about the stool habits of their child, or to the intervention group, where the healthcare professionals will assess the stool habits using diapers.

### What are the possible benefits and risks of participating?

Since healthcare professionals conduct a thorough health check with every child admitted, children are under excellent supervision and receive the best care possible. It is also beneficial for the mothers of the sick children, since they are in close contact with the professionals, which gives them ample of opportunity to ask questions and be reassured that their child is taken care of. There are no risks associated with using diapers in children.

### Where is the study run from?

Nutritional Rehabilitation Center of the Queen Elisabeth Central Hospital in Blantyre, Malawi

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

The study will start in October 2013 and run until January 2014

Who is funding the study?

The study will be funded by the SickKids Foundation, Toronto, Canada

Who is the main contact?

Dr Wieger Voskuil, MD, PhD

## Contact information

### Type(s)

Scientific

### Contact name

Dr Wieger Voskuil

### Contact details

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Stool frequency in Severe Acute Malnutrition: a randomized controlled trial comparing maternal stool recall versus a direct stool observation method using diapers

### Acronym

StoolSAM

### Study objectives

Stool output as assessed by the maternal/carer recall method is equivalent to a clinical gold-standard assessment using directly observed diapers in children with severe acute malnutrition (SAM).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

College of Medicine Research Ethics Committee, University of Malawi, 11/10/2013, P.07/13/1429

### Study design

Randomized gold-standard controlled interventional single-centre trial

## Primary study design

Interventional

## Study type(s)

Diagnostic

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

Severe acute malnutrition in children

## Interventions

1. Intervention group: conventional disposable diapers will be put on children and will be checked and changed every two hours by healthcare professionals. Mothers can also request to get the diapers changed within the 2 hours if there was a stool episode.
2. Control group: no intervention

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome(s)

1. Observed stool frequency
2. Stool consistency measured with the help of the Bristol stool chart and the Amsterdam paediatric stool chart (watery/loose/normal/bloody)

In the diaper group, diapers will be checked every two hours over a time period of 3 days. The day starts at 8.00 AM, from then on diapers will be checked at 10.00, 12.00, 14.00, 16.00 and 18.00. During the night (between 18.00 and 8.00), the night nurses are instructed to change the diapers whenever necessary (i.e., when there was an episode of stool) and collect those diapers in a bucket. In the control group, mothers are asked every morning during ward rounds (at around 10.00) about the stool episodes during the previous day with the help of a picture chart ('from sunrise to sunset = yesterday', 'from sunset to sunrise = last night', 'since sunrise').

## Key secondary outcome(s)

The mother's opinion on the preferred stool assessment method (disposable diapers or no diapers). This will be assessed after completion of the study, i.e. on the morning after day 3. We are using a scale from 1-5 (1 = strongly prefer diapers, 5 = strongly prefer verbal recall method).

## Completion date

31/01/2014

## Eligibility

### Key inclusion criteria

All children admitted to the Nutritional Rehabilitation Unit of the Queen Elisabeth Central Hospital in Blantyre, Malawi (MOYO) aged 6-40 months who meet the WHO and Malawi National Guidelines criteria for severe acute malnutrition (SAM) will be eligible to participate in this study:

1. Marasmus = weight-for-height less than or equal to -3 Z-scores (WHO growth standards) OR a mid-upper-arm circumference of <11.5 cm
2. Kwashiorkor = nutritionally induced bilateral pitting edema

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

1. Children who are already potty trained and therefore do not require diapers
2. Circulatory and respiratory instability as assessed by the consulting physician
3. Severe rash in the genital area

**Date of first enrolment**

12/10/2013

**Date of final enrolment**

31/01/2014

**Locations****Countries of recruitment**

Malawi

**Study participating centre**

Queen Elizabeth Central Hospital

Blantyre

Malawi

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**Sponsor information****Organisation**

The Hospital for Sick Children (Canada)

**ROR**

<https://ror.org/057q4rt57>

# Funder(s)

## Funder type

Charity

## Funder Name

SickKids Foundation (Canada)

# 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?
<a href="#">Results article</a>	results	07/06/2017		Yes	No