

# Chilenje Infant Growth, Nutrition and Infection Study

<b>Submission date</b> 28/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/01/2015	<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**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Chilenje Infant Growth, Nutrition and Infection Study

**Acronym**  
CIGNIS

**Study objectives**

Feeding for 12 months with a fortified complementary food will decrease the proportion of stunted children by 30%.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Added 02/09/10:

1. Approved by the University of Zambia ethics committee
2. Approved by the London School of Hygiene and Tropical Medicine ethics committee

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Infant growth faltering

**Interventions**

One of two locally developed complementary foods fed for 12 months

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Prevalence of stunting

**Key secondary outcome(s))**

1. Body composition
2. Indices of iron (Fe), zinc (Zn), copper (Cu), selenium (Se) and vitamin A status
3. Morbidity
4. Gastrointestinal permeability
5. Response to oral polio vaccine
6. Behavioural development
7. Development of chronic childhood viral infections

**Completion date**

30/06/2008

**Eligibility**

**Key inclusion criteria**

Infants aged 6 months and resident in Chilenje, Zambia whose mothers agree:

1. To prepare and feed their infants for 12 months the food supplied to them
2. To attend the specified clinic or home visits
3. To let their infants undergo specified urine collection and blood sampling
4. To permit the infants to be tested for human immunodeficiency virus (HIV)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 months

**Sex**

All

**Key exclusion criteria**

Non-fulfilment of inclusion criteria or evidence of chronic disease (active tuberculosis [TB], symptomatic HIV)

**Date of first enrolment**

20/07/2005

**Date of final enrolment**

30/06/2008

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

United Kingdom

England

Zambia

**Study participating centre**

Nutrition and Public Health Interventions Research Unit

London

United Kingdom

WC1E 7HT

# Sponsor information

## Organisation

Bill and Melinda Gates Foundation (USA)

## ROR

<https://ror.org/0456r8d26>

# Funder(s)

## Funder type

Charity

## Funder Name

Bill and Melinda Gates Foundation (USA) - (ref: 37253)

## Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

## Funding Body Type

Government organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United States of America

## Funder Name

DSM (South Africa)

# Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Results article</a>	results	01/05/2011	Yes	No	
<a href="#">Results article</a>	results	01/02/2012	Yes	No	
<a href="#">Results article</a>	results	01/03/2012	Yes	No	
<a href="#">Results article</a>	results	01/11/2014	Yes	No	
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes