







# Effectiveness of approaches to deliver integrated solutions for optimal child growth and development in Tanzania

<b>Submission date</b> 01/10/2017	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol added
<b>Registration date</b> 03/10/2017	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 29/04/2021	<b>Condition category</b> Not Applicable	 Raw data not yet added
		 Study completed

## Plain English Summary

### Background and study aims

It is estimated that that 20 million low-birth-weight babies are born each year, 314 million children under 5 years of age experience mild to severe stunting, and over 200 million children are not meeting their developmental and cognitive potential. Reducing the number of Tanzanian children facing these early life adversities is vital given the large negative long-term consequences of early developmental delays in terms of individual earnings and social capital. Children experiencing in utero or early childhood adversity generally enrol later in school (if they enrol at all), perform poorly on academic tests, complete less education than their peers, and have reduced personal income later in life. Accordingly, improving early life environments will likely not only improve child growth and development in the short run, but also contribute to more educated and productive future societies. The aim of this study is to assess a child growth and development intervention package delivered by community health workers (CHWs) in Morogoro Region, Tanzania. The study also looks at whether conditional cash transfers for antenatal care and well-child clinic visits improve child growth and development.

### Who can participate?

Pregnant women and mothers/caregivers of infants under 1 year of age

### What does the study involve?

Participating villages are randomly allocated to one of three groups. In the first group CHWs deliver the intervention package once a month in the home. In the second group CHWs deliver the intervention package once a month in the home and also conditional cash transfers to promote antenatal care and child growth monitoring clinic visits. The third group receive standard care. Participants receive the interventions for a duration of 18 months. The total duration of follow-up is 18 months. Child development and height are assessed at 9 and 18 months.

What are the possible benefits and risks of participating?

The benefit of participating is that children may receive health and development benefits from the intervention. There are no expected risks associated with participation.

Where is the study run from?

Ifakara Health Institute (Tanzania)

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

March 2017 to May 2019

Who is funding the study?

Grand Challenges Canada

Who is the main contact?

1. Dr Honorati Masanja
2. Dr Christopher Sudfeld

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Honorati Masanja

**Contact details**

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**Type(s)**

Scientific

**Contact name**

Dr Christopher Sudfeld

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**

R-SB-POC-1707-09024

## **Study information**

### **Scientific Title**

Effectiveness of approaches to deliver integrated solutions for optimal child growth and development in Tanzania

### **Study hypothesis**

1. Community health worker (CHW) delivery of evidence-based nutrition and responsive stimulation intervention package improves child growth and development.
2. Cash transfers conditioned on antenatal care and well-child clinic visits improve child growth and development.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Ifakara Health Institute IRB, 31/03/2017, ref: 007-2017
2. National Health Research Ethics Sub-Committee, 17/07/2017, ref: NIMR/HQ/R.8a/Vol.IX/2538
3. Harvard School of Public Health IRB, 20/07/2017, ref: IRB17-1001

### **Study design**

Single-centre cluster-randomized trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

Community

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **Condition**

Child growth and development

### **Interventions**

This study is a pilot cluster-randomized trial to evaluate integrated supply and demand sided platforms to deliver a child growth and development intervention package in Morogoro Region,

Tanzania. 12 villages will be randomized within strata of peri-urban (6 villages) and rural (6 villages) to one of three study arms:

1. CHWs Only: CHWs deliver a nutrition and responsive stimulation caregiver intervention package once a month in the home
2. CHWs + CCT: CHWs deliver a nutrition and responsive stimulation caregiver intervention package once a month in the home plus conditional cash transfers to promote ANC and child growth monitoring clinic visits
3. Control: Participants will receive standard of care

Villages receive the randomized treatment for a duration of 18 months. The total duration of follow-up is 18 months.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Child development measured by the Bayley Scale of Child Development, 3rd edition at 9 and 18 months
2. Child height-for-age z-score assessed at 9 and 18 months

### **Secondary outcome measures**

1. Attendance to ANC and child health visits assessed by health cards at 9 and 18 months
2. Caregiver parenting knowledge assessed by the Caregiver Knowledge of Child Development Inventory at 9 and 18 months
3. Child weight-for-height z-score assessed at 9 and 18 months
4. Child weight-for-age z-score assessed at 9 and 18 months

### **Overall study start date**

01/03/2017

### **Overall study end date**

10/05/2019

## **Eligibility**

### **Participant inclusion criteria**

1. The trial will be conducted in 12 village clusters which will include ~600 mother/caregiver-infant pairs
2. During the study recruitment time period, pregnant women and mother/primary caregiver of an infant <1 year of age are eligible for enrollment
3. All mothers/primary caregivers must provide informed consent

### **Participant type(s)**

Healthy volunteer

### **Age group**

Mixed

### **Sex**

Both

**Target number of participants**

12 village clusters with an estimated 50 mother/caregiver-infant pairs in each cluster

**Total final enrolment**

593

**Participant exclusion criteria**

Infants <1 years at the time of enrollment with signs of severe physical or mental impairments

**Recruitment start date**

14/09/2017

**Recruitment end date**

31/10/2017

## Locations

**Countries of recruitment**

Tanzania

**Study participating centre**

Morogoro Region, Tanzania

Tanzania

-

## Sponsor information

**Organisation**

Ifakara Health Institute

**Sponsor details**

Plot 463, Kiko Avenue Mikocheni

Dar es Salaam

Tanzania

PO Box 78 373

**Sponsor type**

Research organisation

**Website**

<http://ihi.or.tz/>

ROR

https://ror.org/04js17g72

## Funder(s)

### Funder type

Government

### Funder Name

Grand Challenges Canada

### Alternative Name(s)

Grands Défis Canada, GCC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Canada

## Results and Publications

### Publication and dissemination plan

The trialists plan to publish the results in a high-impact peer-reviewed journal around 1 year after trial end.

### Intention to publish date

31/08/2020

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from [csudfeld@hsph.harvard.edu](mailto:csudfeld@hsph.harvard.edu). Deidentified individual participant data (including data dictionaries) may be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data may be made available upon publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal and obtain the necessary ethical approvals.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	27/05/2019	29/05/2019	Yes	No

<a href="#">Results article</a>	results	13/12/2020	02/02/2021	Yes	No
<a href="#">Results article</a>		01/04/2021	29/04/2021	Yes	No