ISRCTN10323949 https://doi.org/10.1186/ISRCTN10323949

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

Submission date
01/10/2017

Recruitment status
No longer recruiting

Registration date
03/10/2017

Overall study status
Completed

Last Edited
29/04/2021

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

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
Ifakara Health Institute
Plot 463, Kiko Avenue
Mikocheni
Dar es Salaam
Tanzania
PO Box 78 373

Type(s)
Scientific

Contact name
Dr Christopher Sudfeld

Contact details
677 Huntington Ave,
Boston
United States of America
02115

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
10/05/2019

Eligibility

Key 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

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

Date of first enrolment
14/09/2017

Date of final enrolment
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. 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?
Protocol article	protocol	27/05/2019	29/05/2019	Yes	No
Results article	results	13/12/2020	02/02/2021	Yes	No
Results article		01/04/2021	29/04/2021	Yes	No