ISRCTN15360698 https://doi.org/10.1186/ISRCTN15360698

Evaluating an early childhood care and education program brought to scale in Ghana

Submission date
15/12/2021

Recruitment status
No longer recruiting

Registration date
17/12/2021

Overall study status
Completed

Last Edited
14/10/2022

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Millions of children in the developing world will not reach their full potential due poor sanitation, nutrition and living in unstimulating environments. Many early childhood care and education programs have been shown to be effective in improving pre-school children's school readiness and health, but few of those which have been adopted by national governments have either (i) been re-evaluated once they're delivered at a national level or (ii) been shown to be effective once they have been.

This study team previously evaluated the International NGO Lively Minds ECCE program in a small efficacy trial in northern Ghana, showing it to be effective in boosting cognition and child health. This program has now been adopted by the government of Ghana, and is being rolled out to 61 districts across the north of the country. In partnership with the government and Lively Minds, we have agreed to evaluate the roll of the program using a randomized control trial framework, randomizing the order in which different districts start to receive the program across a 3 year period.

Who can participate?
Study participants are children aged between 3-5 and either enrolled or due to enrol in pre-school in the coming school term.

What does the study involve?
This study involves taking part in two surveys, one immediately prior to the ECCE program being rolled out to participants district and one two to three terms later, where one term is about three months. As the program is now run by the government of Ghana and part of the government policy, researchers have little to no input in its delivery other than randomizing the order in which it gets rolled out to each district.

What are the possible benefits and risks of participating?
Other than gifts given to survey participants as compensation for their time, there are no benefits for taking part in this study. Taking part in the study entails interacting with interviewers, covering topics such as health and maternal empowerment, which some participants may find uncomfortable.

Where is the study run from?
The study is run from the Institute for Fiscal Studies (UK), in partnership with Yale University (USA), the University of Ghana, and International Poverty Action, Ghana.

When is the study starting and how long is it expected to run for?
June 2021 to September 2024

Who is funding the study?
The study is funded by United States Agency for International Development

Who is the main contact?
Dr Sonya Krutikova, sonya_k@ifs.org.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sonya Krutikova

ORCID ID
https://orcid.org/0000-0003-2488-7489

Contact details
The Institute for Fiscal Studies
7 Ridgmount Street
London
United Kingdom
WC1E 7AE
020 7291 4800
sonya_k@ifs.org.uk

Type(s)
Public

Contact name
Dr Sonya Krutikova

Contact details
Institute for Fiscal Studies
7 Ridgemont Street
London
United Kingdom
WC1E 7AE
020 7291 4800
sonya_k@ifs.org.uk

Additional identifiers

Protocol serial number
AEARCTR-0008500

Study information

Scientific Title
Evaluation of a pre-school program implemented at scale in Ghana

Study objectives
1. The early child care and education program improves child development when implemented at scale.
2. The early child care and education programme increases child height-for-age Z scores (and reduces rates of stunting) when implemented at scale.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 23/10/2021, UCL Ethics Board (University College London, 2 Taviton Street, London, WC1H 0BT, UK; no telephone number provided; ethics@ucl.ac.uk), ref: 21361/001
2. Approved 22/11/2021, Ghana Health Service Ethics Review Board (Research and Development Division, Ghana Health Service, P.O. box MB 190, Accra, Ghana; no telephone number provided; ethics.research@ghsmail.org), ref: 028/09/21
3. Approval pending, Yale Ethics Review board

Primary study design
Interventional

Study design
Unblind multi-centre cluster randomized control trial with 1:1 allocation

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Child health and cognitive and socio-emotional development.

Interventions
The intervention in this trial is the government implementation of the International NGO's Lively Minds Early Child Care and Education program, with the sequence in which different districts start receiving the program randomly allocated by the research team. The program involves child playgroups for pre-school-aged children, the installation of "Tippy Tap" water sources for hand-washing, pre-school teacher training, and a parenting program, and was previously evaluated by the PI in an earlier study (see https://ifs.org.uk/publications/14922 for details).

While the program is scaled to all districts in Northern Ghana, this study focuses on 54 districts (grouped into 9 district groups (DG)) and two cohorts of children, combined into 60 district-cohort pairs. District groups will be enrolled in the study from January 2021 to September 2024 in 5 tranches. In each tranche, one DG is allocated at random into the treatment group and one allocated to the control. District group six is used with different cohorts of children as both a

control and treatment district group - control with the first cohort of children, treatment with the second. The control DG in each tranche will begin to receive the program 2 to 3 terms after being enrolled into the study after all data collection has been completed.

Intervention Type
Behavioural

Primary outcome(s)
Measured 2 to 3 academic terms (6 - 9 months approximately) after treatment commences:
1. Child cognition as measured using the emergent numeracy, emergent literacy and executive functioning tasks in the IDELA as well as items relating to the same domains from the Harvard Laboratory for Development Studies
2. Child health, as measured using height/weight for age and height for weight Z score
3. Child socio-emotional development, as measured by the externalizing, internalizing and pro-social domains of the Strengths and Difficulty questionnaire and the the socio-emotional items in the IDELA

Key secondary outcome(s)
Measured 2 to 3 academic terms (6 - 9 months approximately) after treatment commences:
1. Maternal mental health (Kessler-10 and WEMWBS) and knowledge of ECCE
2. Teacher knowledge, motivation and teaching quality (measured through classroom observations)
3. Parent-child investment, as measured by quality of the home environment (FCI and HOME) and the parent-child relationship (CPRS)
4. WASH practices in the home
5. Acute Malnutrition measured by MUAC

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. Aged between 3 and 5 years
2. Enrolled in the 1st year of preschool or planning to enrol in a sample preschool in the coming term (i.e. they must be in the preschool for the whole duration of the treatment).

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit

5 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
17/01/2022

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
Ghana

Study participating centre
Ghanaian Education Service
M45 Ministries Accra
Accra
Ghana
M45

Sponsor information

Organisation
United States Agency for International Development

ROR
https://ror.org/01n6e6j62

Funder(s)

Funder type
Government

Funder Name
United States Agency for International Development

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be stored in a publicly available repository, either the UK Data Service or the World Bank Microdata archive (conditional on funder requirements). Archived data will be fully anonymous, and consent for the archiving process is sought as part of the participant consent process. The data will be available for research purposes only.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/10/2022	14/10/2022	Yes	No