

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

Submission date 15/12/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/10/2022	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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@ghsml.org), ref: 028/09/21
3. Approval pending, Yale Ethics Review board

Study design

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

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

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

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 measure

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 socio-emotional items in the IDELA

Secondary outcome measures

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

Overall study start date

01/06/2021

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

Age group

Child

Lower age limit

3 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

72 clusters with 5 schools per cluster and 9 children per school, providing a sample of 3240 children in total (45 participants per cluster).

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

Sponsor details

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United States of America
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Sponsor type

Government

Website

<https://www.usaid.gov/>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/09/2025

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