

Early childhood development for the poor: impacting at scale

Submission date 02/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/06/2020	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

The first three years of life lay the basis for lifelong outcomes due to the rapid development of the brain. During this time, children are also vulnerable to negative influences of factors such as malnutrition, illness and unstimulating environments. These factors may be caused by poverty and may have a detrimental effect on children's health and development, including physical, cognitive, language and motor development. Research has shown that approaches to early childhood development (ECD) that involve psychosocial stimulation and/or nutrition are effective in mitigating the influences of negative factors. Our aim is to understand the effects, sustainability and costs of such an approach and the mechanisms needed for these early years' interventions to be effective in poor populations. We need to know how the interventions change beliefs, knowledge and parenting practices as well as the specific investments (in time and resources) that parents and caregivers make in child rearing. The aim of this study is to evaluate two different ways of delivering an ECD intervention together with nutritional information in 192 villages in rural Odisha. Odisha provides an excellent setting for the study as it has low levels of stimulation, high malnutrition, poor developmental outcomes and extreme levels of poverty. The study will permit us to learn the extent to which an early childhood stimulation and nutrition intervention is feasible and effective in improving child health and development in low-income and disadvantaged environments.

Who can participate?

Children aged 7-16 months and their families living in communities in rural areas of Odisha, India.

What does the study involve?

Participating villages are randomly allocated to one of four groups. Families in the first group receive nutritional education through home visits from local women hired and trained for the project (facilitators). Families in the second group receive the stimulation curriculum (mother and child play and learning activities) and nutritional education via home visits from facilitators. Families in the third group receive group stimulation, where the facilitator delivers the stimulation curriculum and nutritional education to a group of mothers and children. Families in the fourth group receive only a basic intervention to strengthen links with existing health and nutritional services (this is also available to the other three groups).

What are the possible benefits and risks of participating?

The benefits include better and more frequent parent-child interactions, improved cognitive, language and motor development of the children, and knowledge gained regarding the importance of psychosocial stimulation and nutrition in the early years. There are no known risks.

Where is the study run from?

Pratham Education Foundation (India).

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

August 2012 to December 2020

Who is funding the study?

National Institutes of Health (NIH), World Bank Strategic Impact Evaluation Fund (SIEF), Economic and Social Research Council (ESRC), Yale University, University of Pennsylvania.

Who is the main contact?

Costas Meghir

Contact information

Type(s)

Public

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Study information

Scientific Title

Early Childhood Development for the Poor: Impacting at Scale - a cluster randomised controlled trial

Acronym

ECD

Study objectives

It is hypothesised that early childhood stimulation and improved parental practices in terms of these practices as well as related to nutrition will have long-term positive effects on child's physical, cognitive, language and motor development. Approaches to child development that involve cognitive and psychosocial stimulation and/or nutrition are effective in mitigating influences of negative factors induced by poverty such as malnutrition, illnesses and un-stimulating home environments.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Yale University Human Subjects Committee, 09/01/2014, ref: 1112009492
2. University College London (UCL), UCL Ethics Committee, 24/02/2012, ref: 2168/002
3. Indian Council of Medical Research (ICMR); 20/03/2013 (ICMR), ref: 5/7/822/2012/RCH
4. University of Pennsylvania (Penn), Office of Regulatory Affairs, 02/01/2014, ref: 815027 IRB#8
5. Pratham Education Foundation (Pratham), FWA for the Protection of Human Subjects, 31/01/2013, ref: FWA00019832
6. Institute for Financial Management and Research (IFMR), Human Subjects Committee, 24/08/2014, ref: IRB00007107; FWA00014616; IORG0005894

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Child development

Interventions

We will carry out a psycho-social stimulation programme coupled with nutrition education that aims to improve interactions between mothers or principal caregivers and their infants/children with the aim of achieving better child outcomes. The ECD intervention follows a systematic weekly curriculum based on the natural developmental stages of the child. Alternative service provisions include delivery of the curriculum by local women either (i) during weekly individual home visits to mother and child, or (ii) in a suitably modified way, within the context of weekly mother-child group meetings. These two versions of the ECD intervention will be coupled with an educational nutritional intervention. The delivery of these interventions will last for 24 months and will be evaluated using a randomised control trial. We will collect data on child

development outcomes and detailed maternal and household level data before the start, halfway through and at the end of the intervention. Our focus will be on communities in rural areas of Odisha and will involve children aged 7-16 months. We propose to implement and compare four variants of our intervention:

1. Provision of education on nutritional issues (hereafter referred to as NE): Regular visits to the home will be carried out by local women hired and trained for the project (henceforth referred to as educators) to deliver the nutritional education curriculum, which will be designed to produce positive changes in food choice, preparation and storage.
2. Individual Stimulation via Home Visits (IS) (+ NE): Weekly visits to the home will be carried out by local women hired and trained for the project (henceforth referred to as facilitators) to deliver the stimulation curriculum and involve mother and child in play and learning activities.
3. Group Stimulation (GS) (+ NE): In this variant, the facilitator will deliver a specially-designed version of the stimulation curriculum to a group of mothers and children. The group will meet weekly and is planned to have a maximum of 9 mothers and children.
4. Health and Nutritional Services Link (HNSL): A basic intervention that strengthens links with the existing services will be available to all study arms, including the control group. The aim of offering the basic service to all is to create a baseline where the current policy framework is well understood. We then measure our intervention over and above a status quo, which encourages take-up of policy as is now.

The evaluation design will be based on a cluster randomized trial in which a target sample of 192 villages with the selected facilitators/educators will be allocated randomly to intervention variants 1 to 3 described above and a control group. In total, there will be 48 villages in each intervention arm, including in the control.

Within each village we intend to treat and collect data on and offer the intervention to all children aged 7-16 months at the start of the intervention. Our initial estimate was that in the average study community there would be 7.5 children in this age group. This estimate was based on data from our sanitation project in similar villages. However, in our final sample of 192 villages, this average was around 14. Since our budget did not allow for treatment of so many more children, we adopted the following approach:

1. In villages with 8 children or less (one third of the 192 villages), we took all children to be part of the study.
2. In the remaining villages, we chose one eligible child at random and thereafter included in the sample those additional seven children that live geographically speaking closest to the randomly chosen child.

This approach ensures that even in villages with relatively large populations and spread, our target children would come from the same neighbourhood, hence facilitating intervention implementation. Similarly, it allows to have a clear criteria for inclusion into (exclusion out of) the intervention. On the one hand, we have a clear age cut-off, on the other hand a geographical clustering. It may also improve the quality of the intervention if all mothers of children in a particular age group in the villages interact and provide social support for each other regarding child-rearing practices. Finally, this will be consistent with scaling-up the program to full coverage.

Communities are randomised to the different intervention arms as we expect the interventions to have spillover within villages. By randomizing across communities we allow for possible spillovers within villages that may increase the overall impacts.

Part of our evaluation design is to measure such spillovers, to understand the importance of this conduit for propagating and reinforcing good practice in child rearing. To do so, we will in addition to our target children, interview households of mothers with children below and above the target age range (2-6 months and 17-20 months). In total, 767 such spillover households will be included in the sample.

Intervention Type

Behavioural

Primary outcome(s)

1. Children's child cognitive, language and motor development - We will assess cognitive, language and motor development at the time of the follow-up surveys using the third version of the Bayley Scales of Infant and Toddler Development (Bayley-III), suitably adapted for the context.
2. Children's nutritional status - We will measure height and weight both at baseline and at the two follow ups, using standard methods. We will also collect information on feeding practices by food type, frequency and quantity.
3. Children's morbidity - We will collect data on the incidence of diarrhoea, fever and respiratory infections using the definitions of the WHO as measures of morbidity. We will also collect records of immunisations.

Key secondary outcome(s)

1. Child rearing practices: level of stimulation in the home - The presence of toys and learning materials in the house will be assessed together with parental involvement with the child, the child's routines and organisation of the child's time inside and outside the family house. This will be assessed using the Family Care Indicators, developed by UNICEF, and possibly selected subscales of the Home Observation for the Measurement of the Environment (HOME).
2. Maternal knowledge of child rearing practices - We will collect information on the mother's knowledge of nutrition and stimulation, and her beliefs regarding the importance of these for children's development. To test knowledge, we will rely on a selection of items from the Knowledge of Infant Development (KIDI).

Completion date

31/12/2020

Eligibility

Key inclusion criteria

Children aged 7 - 16 months and their families

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Children outside of this age range

Date of first enrolment

27/11/2015

Date of final enrolment

27/11/2017

Locations**Countries of recruitment**

India

Study participating centre**Pratham Education Foundation (Odisha head office)**

Holding no.-1/N/5

Arundoya Nagar

Cuttack

India

753012

Study participating centre**Pratham Education Foundation**

At-Dahipur

Po-Radhaballabhpur

Soro

Balasore

India

756045

Study participating centre**Pratham Education Foundation**

At-Sapanpur

PO-Sisua

Cuttack

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754202

Study participating centre

Pratham Education Foundation
At/Po- Puintala (Near Puintala block)
Balangir
India
767071

Sponsor information

Organisation
Yale University

ROR
<https://ror.org/03v76x132>

Organisation
Institute for Fiscal Studies (UK)

Organisation
The Abdul Latif Jameel Poverty Action Lab (J-PAL) South Asia (India)

Organisation
Pratham Education Foundation-ASER Centre (India)

Organisation
Centre for Early Childhood Education and Development (CECED) (India)

Organisation
University of Pennsylvania (USA)

Funder(s)

Funder type
Government

Funder Name

National Institute of Child Health and Human Development

Alternative Name(s)

NICHHD

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Funder Name

Economic and Social Research Council

Alternative Name(s)

Social Science Research Council, ESRC, SSRC, UKRI ESRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Yale University

Alternative Name(s)

Yale, Collegiate School, Yale College, Universitas Yalensis

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United States of America

Funder Name

University of Pennsylvania

Alternative Name(s)

Penn, Upenn, Academy and Charitable School in the Province of Pennsylvania, College of Philadelphia, University of the State of Pennsylvania, Universitas Pennsylvaniensis

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date