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# Cluster randomised trial of the effects of timing and duration of early childhood interventions in Odisha – India: Study protocol

IFS Working Paper W19/06

Orazio Attanasio
Britta Augsburg
Jere Behrman
Sally Grantham-McGregor
Pamela Jervis
Costas Meghir
Angus Phimister
Marta Rubio-Codina

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

# Cluster Randomised Trial of the Effects of Timing and Duration of Early Childhood Interventions in Odisha – India: Study Protocol

**Authors**[1]
Orazio Attanasio[1,2], Britta Augsburg[1], Jere Behrman[3], Sally Grantham-McGregor[2], Pamela Jervis[1], Costas Meghir[4], Angus Phimister[1], Marta Rubio-Codina[5].

## Abstract

**Introduction**

Many children in developing countries grow up in unstimulating environments, leading to deficiencies in early years' developmental outcomes, particularly cognition and language. Interventions to improve parenting in the first 3 years of life have a clear impact on these outcomes, but the sustainability of effects is mixed, particularly for scalable interventions. There is little evidence of the effect of following-up an early life intervention with another one immediately afterwards. The objective of this study is to help fill this gap.

**Methods and Analysis**

This study is a cluster randomized control trial (CRCT) to assess the effects of improvements in preschool quality, following directly after a separate CRCT assessing a stimulation and nutritional educational intervention (AEA RCT Registry: 0000958). Using the same sample as the original study (N=2170), each of the original 4 study arms are randomly divided into treatment and control forming 8 study arms. Primary outcomes are cognition, language and school readiness measured using subscales of the Wechsler Preschool and Primary Scale of Intelligence test IV for cognition and language and the Daberon-2 screening for school readiness. Secondary outcomes include the Strength and Difficulties Questionnaire for behavioural problems and pro-social behaviour, preschool quality, indicators of compliance, such as enrolment and attendance in Anganwadi Centres, as well as child growth. We will estimate unadjusted and adjusted intent-to-treat effects using semi-parametric estimators. We will also consider differences by gender of the subject child and the education of the mother/principal caregiver.

**Ethics and dissemination**

Study protocols have been approved by ethics boards at University College London (IRB 2168/014), University of Pennsylvania (IRB 815027), Yale University (IRB 1112009492) and Pratham Ethics Committee (IRB PEF/AC-1/2).

**Trial registration number**

AEA RCT Registry: 0003161, ISRCTN: 12916148

[1] Authors listed in alphabetical order

# Introduction

The importance of early life has been highlighted in three series on Early Childhood Development (ECD) published in *The Lancet* between 2007 and 2016[1-7] and in many other publications.[8-18] One key conclusion of this burgeoning literature is that stimulation interventions can be life-changing with long-run persistent effects leading to tangible improvements in quality of life through adulthood. One of the most successful and influential studies has been the well-known home-visiting early childhood stimulation experiment in Jamaica[15-17, 19], which over the years has demonstrated the potential for intervening in very poor and deprived populations with benefits in terms of cognitive and socioemotional skills and wages that lasted more than two decades [15-17, 19].

Though early life is increasingly emphasized as the foundation for individual and societal successes, there are important yet unanswered questions about which interventions have the greatest promise. Child development is a set of complex processes involving cognitive, language, motor, socio-emotional and behaviour-regulation development. Development is affected by both genetics and interactions with the environment, including at home and in pre-schools. In particular, exposure to risks associated with poverty in the early years can have sustained effects on brain structure and function[20]. Deficits in cognitive function due to poverty are apparent from the first year of life and increase at least up to 5 years.[21] Different neural functions have different sensitive periods when they are most affected by exposure to certain risks or interventions. Whilst there is some information on the timing of sensitive periods for risks[22] there is less information on the timing for interventions[23].

This leads to some key but understudied questions: Are the impacts of very early interventions sustained, possibly accelerated, when they are complemented by subsequent interventions? I.e. Can fading, often observed after successful interventions, be avoided by continued intervention in the next life-cycle stage and lead to increased improvements? To what extent can early-life deficits be reversed?[24-26] Are there possibilities of subsequent recovery – or faltering for those without early deficits?[27-35] Which are the sensitive periods when achieving improvement is easiest? Is it essential that interventions begin at very early ages? Or is there potential in interventions that start later, when children are older and may be in preschool? Might some interventions be a waste of resources if undertaken too early – or too late? These are central questions, particularly in the context of poverty affecting millions of children, such as in rural India.

In addition to questions about timing and complementarities, another large challenge faced by policy makers in this field is the scalability of specific interventions, for which evidence of impact largely comes from small pilot studies, often implemented in a very controlled manner. Scalable ECD interventions must be conceived with the specificity of a given context in mind and will need to use local and community resources, possibly using the infrastructure of existing services.

In this study, we build on and extend a successful intervention in rural Odisha, India, implemented in the period December 2015-January 2018 (Early trial). That study was based on a population of 192 villages (clusters) selected by stratified random sampling based on district and the number of available children in the target age range. These were randomized within stratum (geographical district) to 4 groups: control, nutritional education, and two implementation models of an early childhood psychosocial intervention (based on Reach Up and Learn[36]): individual stimulation in home visits or group based stimulation in group meetings, both with mothers and children. As part of this study (Late trial), at the end of the Early trial, each arm was re-randomized to an additional treatment of an improved preschool with parenting meetings or to a control receiving the usual care. This design allows us to rigorously address questions like those posed above.

While various forms of ECD interventions have been shown to improve child outcomes, we lack evidence of what a comprehensive program starting in infancy and continuing all the way to the start of school at age 5 years could achieve. How would this program compare to one that starts later only, or to one that starts early but stops on average at 36 months and is not followed-up? All these alternatives should be compared to the no intervention controls. The only randomized control trial of the timing of interventions that the team is aware of was the Abecedarian (ABC).[37] In a much different context, no benefits were found of extending an initial intervention, which lasted from 3 months to 5 years, for a further 3 years after primary school entry. In contrast, we plan to examine which is the most effective age to start an early childhood intervention (comparing one intervention active between an average of 12 to 36 months to one active between 41 to 60 months), and what is the overall effectiveness of assigning

children to both interventions sequentially. The scale of our intervention is much larger, including over 1400 children.

**Objectives of the study**

Early life experiences are an important determinant of long-term outcomes, and ECD interventions can do much to rectify early deficiencies. As discussed above, there remains several key unanswered questions about the optimal timing, duration and scalability of such programs. This trial will directly test these questions with the following primary scientific objectives:

1. Measure the impact on cognition and school readiness of an enhanced preschool program for children aged 3 to 6.

2. Measure the impact on cognition and school readiness of a combined early (1-3) and later (3-6) aged interventions and determine whether interventions reinforce each other.

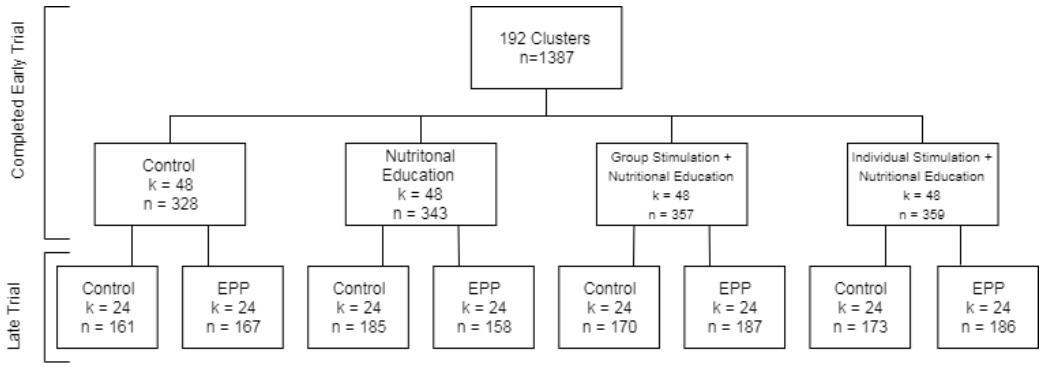
3. Measure whether or not intervention at 3-6 has a higher or lower impact on children's development than intervention at 1-3.

# Methods and Analysis

## Overview of design

The trial is designed by researchers from the Institute for Fiscal Studies (IFS), UK; Yale University, USA; and University of Pennsylvania, USA, implemented by Pratham, India's largest educational NGO. The newly implemented intervention, the Enhanced Preschool Program (EPP), was designed by the Centre for Early Childhood Education and Development (CECED) at Ambedkar University, India together with researchers from IFS and Pratham in collaboration with the Indian Integrated Child Development Service (ICDS). The Late trial has two arms, treatment and control, but will be subdivided into 8 arms once the 4 arms of the Early trial are considered (Figure 1). The unit of randomization is at the village level, and all Anganwadi centres (AWC) in each village are included in the study. The study aims to enrol all target children from the previous trial who have not migrated from the sample area. Figure 2 shows the participant timeline. We will measure primary outcomes at 9 and 18 months after introduction of the EPP in July 2018 when the children will be on average 52 and 61 months respectively. Midline data collection is planned to start in Mid-March 2019[2] and Endline in December 2019.

Figure 1: Trial Design showing completed Early trial and Proposed Late Trial

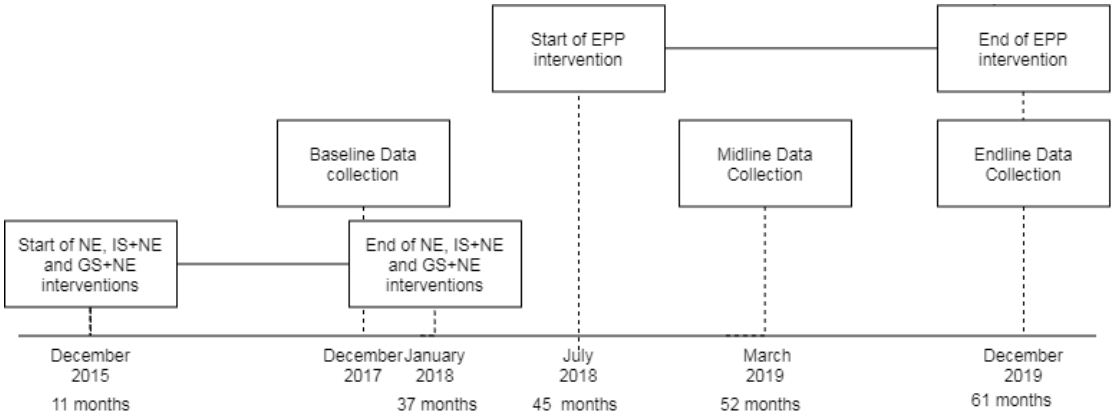



*Note: EPP refers to Enhanced Preschool Program, k refers to number of clusters, n refers to number of children. Sample based on subjects who had not attrited by Endline of the Early trial.*

The choice of villages as the unit of randomization was motivated by 1) this was the unit of randomization in the previous trial 2) children attend AWC within their village 3) AWC are often very close to each other and children can switch between them so AWC level randomization was impossible.

[2] This protocol was first published before the start of Midline data collection.

Figure 2: Participant Timeline




*Note: NE refers to Nutritional Education treatment, IS refers to Individual Stimulation Treatment, GS refers to Group Stimulation treatment.*

It is impossible to know the effects of the earlier treatments a priori. Division into 8 study arms limits the power available to test each hypothesis. If there are no differences between the two stimulation treatments (groups and individual home visits) at the end of the Late trial, they will be pooled to improve power. We will follow the same process for the nutritional education and control arms.

## Participant Eligibility Criteria

The primary study participants will be children who were enrolled in the Early trial. Those children were identified through a household census conducted in mid-2015. Children residing in these villages (or planning to return within six months), who were singletons, aged between 7 and 16 months with no obvious physical or mental disability were eligible.

In the Early trial, information was additionally gathered for 700 "spillover children", who resided in the same villages but were aged just outside of the eligible ages (1 to 7 months and 16 to 22 months at baseline of Early trial). These children will be followed in each survey round with the same measurements as the main study sample.

## Setting and Environment

The trial is set in three districts of Odisha, India; Salipur, Bolangir and Soro. These districts are in the rural parts of Odisha, where most of the population live in conditions of extreme poverty. The sample is majority Hindu (93%), but with a sizeable Muslim minority. Most of the sample household heads are literate (75%), have household members who openly defecate (61%) and around 32% of mothers have less than a primary education.

## Description of Intervention

Currently pre-school services are provided through the Anganwadi program. This program was started by the Indian government in 1975 as part of the ICDS program to combat child hunger and malnutrition[38]. A typical AWC provides supplementary nutrition, non-formal pre-school education, nutrition and health education, immunization, and health check-up and referral services. The centres are run by an Anganwadi worker (AWW), a woman from the local community who more generally is tasked with mobilizing community support for better care of young children, girls and women. The centres are often little more than one room, and host between 8-20 children a day.

The program includes a Pre-School Education component for 3-to-6 years-old children directed towards school readiness and development of positive attitudes towards education. This aims to contribute to the universalization of primary education, by providing children with the necessary preparation for primary schooling and offering substitute care to younger siblings, thus freeing the older ones - especially girls -

to attend school. However, the pre-school aspect of the services is inconsistently implemented and has low awareness in the community[39,40].

To implement the EPP intervention, designed to complement and enhance the existing Pre-School Education component, we collaborated closely with the local state government of Odisha and ICDS. The EPP curriculum has components mirroring the stimulation interventions tested in the Early trial, but include a stronger focus on cognition, language and social-emotional development, additional training and in-service coaching of the AWW and helpers, and increasing parental involvement and engagement.

This approach has two important advantages. First, it builds on existing infrastructure seeking to improve both the childcare practices and the skills of women who already have some formal experience in childcare and who have strong links with local communities. Second, the ICDS are important stakeholders if either Early or Late intervention is to be become part of government programming. If successful, it could form a blue print for a scalable child development program.

*Enhanced Curriculum*

The starting point for the curriculum was the existing ICDS curriculum. This was enhanced drawing on project partners' scientific knowledge and extensive experience working with young children in India. The emphasis was to ensure that the enhanced curriculum had maximum buy-in from current AWW, as well as being suitable for the cultural context.

All activities were developed and piloted in collaboration with our partners. The curriculum aims to promote various dimensions of child development, including language, cognition, early executive functioning, motor and social and emotional development, as well as early literacy and mathematics, general knowledge of the world and creativity. Special emphasis is placed on cognition and language, the developmental domains most affected in disadvantaged children. An over-arching principle is that every child is equal - independent of caste, class, religion or ethnicity. Fundamental to providing an effective early learning environment is having a strong positive relationship between the teacher and child. Time is allocated for the child to explore materials and learn through play. Structured sessions using difficulty scaffolding help ensure that activities fall within each child's proximal zone of development[41]. We use some materials from "tools of the mind" to assist in learning[42] such as pictures of an ear to encourage listening, linking colors and shapes to familiar objects. We also encourage socio-emotional development by emphasising on sharing, taking turns and helping others, as well as teaching empathy.

Activity corners are set up daily in each centre and include looking at books, pretend or role play (e.g. "doll house"), construction (blocks and puzzles) and arts (finger painting, drawing, music). For part of the day the children choose their activity. There is at least one structured learning session daily, when basic concepts such as size, shape, colour, position, difference and similarity and quantity are taught as well as early literacy and numeracy. There is also a story time and singing every day, when language skills are emphasized. The final year of the Reach up and Learn curriculum was used as a further resource for new activities[34].

*Pratham Mentors*

Current AWWs are the main persons responsible for implementing the enhanced curriculum, but Pratham mentors also provide crucial support as in-service coaches and mentors. The requirements to become a mentor are low, with only a secondary level education required and minimal training (10 days initially). Each mentor visits two AWCs twice weekly to help implement the curriculum and to discuss any issues, and are responsible for the trainings, on-going coaching and mentoring. They report to 3-4 senior staff, super-mentors, who are in contact with the research team. All preschool sessions include all children, irrespective of whether they form part of our experimental population. Both the AWWs and the Pratham mentors receive two-day refresher trainings quarterly.

*Parenting Meetings*

Parents are invited monthly to the AWC with their children for ninety minutes. The curriculum for these meetings includes lessons on the importance of language during daily activities, the use of books, how to encourage learning, provide good nutrition and health care, and activities to be practiced at home.

Intervention books are taken home for specific amounts of time to reinforce the activities promoted in the parenting element of the intervention.

*Materials*

The intervention makes use of suitable play materials, including books, puzzles and age-appropriate toys. Where possible these items are produced locally using readily-available materials to keep costs low and scale-up possibilities high. Books were printed in Delhi.

# Outcomes

We will make comprehensive assessments of the children's cognition, language and school readiness, behaviour, nutritional status, AWC (and private preschool) attendance as well as AWC quality. All measures will be translated into Oriya and piloted. Where necessary they will be modified to be appropriate for Odisha's culture without changing the basic constructs of the items. All testers will be trained and inter-observer reliability assessed, and they will only begin testing when satisfactory (>0.9) levels of reliability are attained. Where appropriate we will look at summary outcome measures created by combining items using an exploratory factor analysis.

Additionally, we will gather information on household characteristics, family care information, the home environment, maternal depressive symptoms, wellbeing, social networks, knowledge and beliefs about child development.

## Primary outcomes

**Cognition and language**: We will use the Wechsler Preschool and Primary Scale of Intelligence IV[44,45] to assess cognition and language. The WPPSI is used internationally to assess intellectual function and contains the following subscales: Verbal Comprehension Index, Visual Spatial Index, Working Memory Index, Fluid Reasoning Index, and Processing Speed Index. From these, we will use the Verbal Comprehension Index, Visual Spatial Index and Working Memory Index and one task from the Fluid Reasoning Index, and one task from the Processing Speed Index.

**School readiness**: This will be assessed using two instruments. First, we will use a selection of age-appropriate areas in the Daberon-II Screening for School Readiness test[46], a tool developed to sample pre-academic knowledge assessing body parts, colour concepts, number concepts, prepositions, following directions, general knowledge, visual perception, gross motor development and categories areas. From these, we will use all except the motor development scale.

Second, we will use the School Readiness Instrument (SRI) designed by the World Bank India. This measures pre-number concepts, sequential thinking, classification, number readiness, language skills and reading readiness. The tool is currently being modified by CECED to make it more comprehensive and will be used if completed by the time of the Endline data collection.

## Secondary Outcomes

**Behaviour**: We will assess behavioural problems and prosocial behaviour by parental report with the Strength and Difficulties Questionnaire[47], which contains the following subscales: Emotional symptoms, Conduct problems, Hyperactivity/inattention, Peer relationships, Pro-social behaviour. These will be condensed into externalising and internalising problems and pro-social scales.

**AWC Quality:** This will be assessed by a new tool developed for the study which combines parts of three instruments. From the Classroom Assessment Scoring System (CLASS) we will use the dimensions that focus on the quality of teacher-child interaction: positive and negative climate, instructional learning formats, concept development, quality of feedback and language modelling. From the Early Childhood Education Rating Scale (ECERS) we will use the subscales/items focusing on personal care routines and activities. From the Early Childhood Education Quality Assessment Scale (developed by CECED) we will use the activities observation module, as well as measuring the physical conditions of the AWC such

as the provision of washing facilities, seating arrangements, use of space, etc. This section also focuses on the role of the teacher, class composition and teacher-child ratio.

**Preschool Enrolment and Attendance:** Measured using indicator variables on attendance and enrolment in the past 7 days. A minority of children may attend private preschools, instead of the AWC and attendance at these will also be measured.

**Compliance**: Compliance will be measured by the attendance to the training by the AWWs and Pratham mentors and attendance to the AWCs by the Pratham mentors and completion of a report for every day spent in the centre.

**Height and Weight**: As nutritional education was an arm in the Early trial, anthropometric measures will be conducted to assess height-for-age, weight-for-age, and weight-for-height z scores using standard procedures.[48]

## Randomization and blinding

We randomized half of each experimental arm in the Early trial to the EPP, implying 96 communities are included in the new intervention, while the remaining 96 will not be included. Clusters were randomized within treatment arm of the Early trial to ensure balance.

Randomization was conducted by the coordinating team at the IFS using a random number generator in Stata 14 with a reproducible seed. Trial participants cannot be blinded to their own treatment. Cluster assignments will be kept in separate datasets from the analysis sample, stored at IFS, and no testers or surveyors will have access to the assignment. All tests and interviews will be conducted in the homes so that no signs of the treatment will be on view.

## Sample Size and Power

The primary sample size comes from the Endline sample from the Early trial (192 clusters and 1387 sample children). The minimum detectable effect sizes for each of the main hypotheses (for pooled early treatments) are given in Table 1 below and are calculated using a standard formula[49] for a two-tailed test, a compliance rate of 80%, an assumed 5% attrition rate and intra-cluster correlation of 0.04 (found in the first phase of the trial). These estimates are conservative as they do not account for improvements in precision from including covariates in the estimation.

## Analysis Plan

*General Analysis Approach*

The main test outcomes will be scaled using test norms in the first instance, and alternative internal standardizations will be considered if these are deemed inappropriate. We will analyse participants within an intent-to-treat framework, and include unadjusted comparison of means and SDs for all primary hypotheses. Factor variables will be created from the principle factor of exploratory factor analyses. All data and files used to estimate our parameters of interest will be publicly available once the trial is complete. As described above, in the case of no difference in long run impacts between stimulation arms they will be pooled to increase power, with the same being true for non-stimulation arms. Children who show signs of disability (marked as having a score less than 3 SD from the control mean) will be excluded from the analysis.

*Heterogeneity of Impacts*

We will examine how the impacts vary by gender of the child and by education of the mother/primary caregiver.

*Parameters of Interest*

There are several key parameters of interest. Letting $Y_i$ denote the outcome variable for child $i$, and $T_{i1}$ be a dummy variable equal to 1 if child $i$ was assigned to either stimulation arm (IS or GS) in the earlier

trial, and $T_{i2}$ be a dummy variable equal to 1 if child $i$ was assigned to treatment in the current intervention. The primary estimation equation for the combination of the two trials then becomes the following:

$$Y_i = \alpha + \beta_1 T_{i1} + \beta_2 T_{i2} + \beta_3 T_{i1} T_{i2} + \alpha \boldsymbol{X} + \varepsilon_i$$

The parameters of interest are $\beta_1, \beta_2 \; and \; \beta_3$ and their linear combinations. These are described in Table 1 along with the minimum detectable effects given the sample sizes in each group from the first trial. $\boldsymbol{X}$ is a vector of additional controls given below.

*Table 1.*

| **Test** | **Interpretation** | **Minimum Detectable Effect** |
|---|---|---|
| $\beta_1 = 0$ | Conditional Average Treatment effect for the Early trial stimulation treatment, conditional on not being entered into the EPP | 0.26 SD |
| $\beta_2 = 0$ | Conditional Average Treatment effect for Enhanced Preschool Program, conditional on not being part of the earlier stimulation treatment arms. | 0.27 SD |
| $\beta_3 = 0$ | Additional effect of the Enhanced Preschool Program from also being a part of a stimulation treatment arm, above and beyond its own effect (total effect is $\beta_2 + \beta_3$) | 0.38 SD |
| $\beta_2 = \beta_3$ | Treatment effect of the Early trial vs. the treatment effect the second phase. | 0.27 SD |
| $\beta_1 + \beta_2 + \beta_3 = 0$ | Combined effects of early and late interventions | 0.26 SD |

To recover the average treatment effect of the EPP we will also compare the treated vs control for the second phase only:

$$\gamma = E(Y|T_{i2} = 1) - E(Y|T_{i2} = 0)$$

The power for this estimation is 0.19 SD.

When looking at a dichotomous outcomes we will report risk ratios as recommended by CONSORT using differences in means.

*Testing and estimation*

Owing to the large number of hypothesis (combined with the number of outcomes) we will compute the Romano-Wolf stepdown p-values to adjust for multiple hypothesis testing. Hypothesis will be arranged within families of outcomes (e.g. within cognitive domains of the WPPSI).

To increase the precision of our estimates we will control for a series of covariates, as per CONSORT guidelines:

- District
- Tester ID
- Child's age
- Child's sex
- Child's Age's and Stages Questionnaire Scores at Baseline of initial trial (7-16 Months)
- Mother's schooling level
- Mother's Raven's Test score

When analysing the second phase of the trial, we will additionally control for child development at baseline of the extension trial, assessed using the Bayley III test.

*Differential attrition*

We will carefully track sample children to minimize attrition, and try to capture all sample children in each round. We will check for balance across baseline characteristics for attrited and non-attrited children, and if a significant difference is found we will conduct a sensitivity analysis using "worst case" imputation bounds. This is summarized by Manski[49] and Duflo et al[50]. If attrition is high, we may also consider semiparametric weighting using baseline characteristics.

*Interim Analyses*

We plan to conduct a midline survey in March-May 2019 to track the progress of sample children and the quality of preschools. The analysis described above will be conducted at Midline and Endline.

*Stopping Rules*

Whilst there is always a risk of unintended consequences in all types of trials, in this sort of intervention such a risk is minimal. However, if there is any clear evidence of harm then the study will halt under international ethical guidelines for medical research.

*Additional Analysis*

This is a large study with many collaborators, and the data gathered will be able to answer more scientific questions than those outlined in this protocol. The study teams expects to conduct and publish such additional analyses.

**Ethics**

The trial is overseen by independent ethics review boards, which have reviewed the study protocols. Particular consideration will be given to potentially vulnerable people or groups, especially children, and informed consent will be acquired by Pratham Staff from all parents of participating children before the commencement of any data collection, and that they can stop participating at any time without providing a reason. Appendix A1-A3 shows model consent forms. Any reports of abuse or dangers to children will be reported to relevant local authorities.

All important protocol modifications will be communicated to all relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals).

WHO Data set

| | |
|---|---|
| Primary Registry and Trial Identifying Number | AEA RCT Registry: 0003161 |
| Date of Registration in Primary Registry | 21st August 2018 |
| Secondary Identifying Numbers | ISRCTN: 12916148 |
| Source(s) of Monetary or Material Support | ERC, ESRC, World Bank, Cowles Foundation, Dubai Cares, Jacobs Foundation. |
| Primary Sponsor | The Institute for Fiscal Studies |
| Secondary Sponsor | N/A |
| Contact for Public Queries | Angus Phimister: angus.phimister@ifs.org.uk<br>The Institute for Fiscal Studies |

| | |
|---|---|
| | Tel: 020 7291 4800<br>7 Ridgmount Street<br>London<br>WC1E 7AE |
| Contact for Scientific Queries | Prof Orazio Attanasio (o.attanasio@ucl.ac.uk)<br>Drayton House<br>30 Gordon St<br>Kings Cross<br>London<br>WC1H 0AX<br>United Kingdom |
| Public Title | Testing the effect and timing of early childhood interventions for child development from ages 3-5 |
| Scientific Title | Cluster Randomised Trial of the effect and Timing and Duration of Early Childhood Interventions in Odisha, India |
| Countries of Recruitment | India |
| Health Condition(s) or Problem(s) Studied | Child development |
| Interventions | Enhanced Preschool Curriculum against no treatment. |
| Key Inclusion and Exclusion Criteria | The primary study participants of the study are children from Early Trial (ISRCTN18111205). Those children were identified through a household census conducted in mid-2015. Children residing in these villages (or planning to return within six months), who were singletons, aged between 7 and 16 months and had no obvious physical or mental disability were eligible. |
| Study Type | Interventional, open label cluster randomized control trial. |
| Date of First Enrolment | 13/05/2018 |
| Sample Size | 1427 children from first trial eligible, 1387 enrolled. |
| Recruitment Status | Complete |
| Primary Outcome | Assessed at 52 and 61 months.<br>1. Cognitive development assessed using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI):<br>2. School readiness, assessed using either or both of the following:<br>2.1. Daberon-II Screening for School Readiness test (DABERON-2)<br>2.2. School Readiness Instrument (SRI) |
| Key Secondary Outcomes | 1. Behavioural problems and prosocial behaviour Strength and Difficulties Questionnaire<br>Assessed at 52 and 61 months<br><br>2. Preschool Quality.<br>New tool developed for study from the Classroom Assessment Scoring System, Early Childhood Education Rating Scale and Early Childhood Education Quality Assessment Scale<br>Assessed after 9 and 18 months |

| | |
|---|---|
| | 3. Preschool Enrolment and Attendance: Measured using indicator variables on attendance and enrolment in the past 7 days. Assessed after 9 and 18 months<br><br>4. Program Compliance measured by the attendance to the training by the Anganwadi workers and intervention implementers<br><br>5. Height and Weight<br>anthropometric measures will be conducted to assess height-for-age, weight-for-age, and weight-for-height z scores using standard procedures. Assessed at 52 and 61 months |
| Ethics Review | Approved. University College London (IRB 2168/014), University of Pennsylvania (IRB 815027), Yale University (IRB 1112009492) and Pratham Ethics Committee (IRB PEF/AC-1/2) |
| Completion date | December 2019 |
| Summary Results | n/a as trial incomplete |
| IPD sharing statement | The data collected in the study will be publicly distributed along with critical documents (ie, protocols and questionnaires) following the publication of the primary results from the trials, which is expected to be within 24 months of the final data collection date. |

**Author Affiliations**
1 Institute for Fiscal Studies
2 University College London
3 University of Pennsylvania
4 Yale University
5 Inter-American Development Bank

**Author Contributions**
All authors conceptualised and designed the study and drafted the initial manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

**Corresponding Author**
Angus Phimister (angus_p@ifs.org.uk).
The Institute for Fiscal Studies
Tel: 020 7291 4800
7 Ridgmount Street
London
WC1E 7AE

**Protocol Version**
Version 1: 8/3/2019

**Funding**
The project leading to this application has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation programme (Grant No 695300 - HKADeC - ERC-2015-AdG/ERC-2015-AdG). The support of the Economic and Social Research Council (ESRC) is gratefully acknowledged (ES/M010147/1). The support of the World Bank Early Leaning Partnership is also gratefully acknowledged. The support of the Cowles

Foundation is gratefully acknowledged. Funded by the Jacobs Foundation (Klaus J. Jacobs Research Prize 2016). The support of Dubai Cares is also gratefully acknowledged.

**Competing Interests**
None.

**Data sharing statement**
The data collected in the study will be publicly distributed along with critical documents (ie, protocols and questionnaires) following the publication of the primary results from the trials, which is expected to be within 24 months of the final data collection date.

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