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Testing the effect and timing of early childhood interventions for child development from ages 3-5

Submission date
07/08/2018

Recruitment status
No longer recruiting

Registration date
09/08/2018

Overall study status
Completed

Last Edited
21/08/2018

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Stimulation interventions for children, which are interventions that engage children in games and activities and encourage parents to do the same, are of great importance in early life. These interventions can be life-changing, improving quality of life through adulthood. They aim to break the cycle of poverty from generation to generation, where having a poor start in life leads to poorer outcomes throughout life, and to offer equal opportunities for all.
There are still some issues to address with this, including:
1. How can we design Early Childhood Development Interventions (ECD interventions) that can reach large numbers of poor populations in a sustainable way?
2. When should we intervene in childhood development and for how long?
3. Can ECD interventions be adopted in rural South Asia, where half of the world's children under 5 who are not predicted to reach their development potential live?
This study aims to address these questions by building on a previous study (https://www.isrctn.com/ISRCTN18111205). In this previous study, we ran an ECD intervention with home visits and group sessions. In this study, we provide improvements in preschools for preschool age children in the same groups who participated in the last study, with the aim of further addressing the above questions.

Who can participate?
Children who were a part of the initial trial (https://www.isrctn.com/ISRCTN18111205)

What does the study involve?
Participating villages from the previous trial are randomized into either the intervention or control groups. Preschools in intervention villages will receive an enhanced preschool curriculum, developed by child development experts at the Centre for Early Child Education and Development at Ambedkar University Delhi, with additional training for preschool teachers, additional material for teaching classes and the support of a local woman hired and trained for the project (Pratham Mentors) 2 days a week. These mentors will also run parenting meetings

with the parents of all the children in the preschool on child development to encourage parental engagement with the program. Villages in the control group will have access to the same services as they had previously.

What are the possible benefits and risks of participating?
The possible 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 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?
January 2018 to July 2020

Who is funding the study?
1. The Jacobs Foundation Prize (Switzerland)
2. World Bank Early Learning Partnership (USA)
3. Economic and Social Research Council (ESRC) (UK)
4. European Research Council (ERC) (Belgium)
5. Dubai Cares (UAE)

Who is the main contact?
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Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Cluster Randomised Trial of the effect and Timing and Duration of Early Childhood Interventions in Odisha, India

Study objectives
Early childhood stimulation and improved parental practices, in terms of this and 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)
University College London Research Ethics Committee, 03/05/2018, Project ID: 2168/014

Primary study design
Interventional

Study design
Interventional cluster randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Child development

Interventions
This intervention is a direct follow on from a previous trial run with the same sample of children which ran from December 2015 to January 2018 (ISRCTN18111205). In the project extension, we randomised half the communities of each of the 4 earlier experimental arms (which had 48 clusters each) into a new treatment using the statistical program Stata 14. This implies that there are 96 clusters in both treatment and control.

The intervention group will receive an enhanced preschool program (EPP) in their local Anganwadi centres, accompanied by parenting classes embedded in currently existing parental meeting at the centre. Intervention centres will receive all the materials required to implement the enhanced curriculum, and the assistance of a Pratham Mentor who will attend each centre 2

days per week for 18 months. The control group will continue to have access to the same Anganwadi centre services as they did before the start of the trial. The intervention is planned to last from the 16th of July 2017 to the 6th of January 2020.

The initial phase of the trial had three data collection rounds: a baseline survey (completed and report is available), one at midline (December 2016) and one at endline (December 2017). In this second phase, we will build on this data collection with two further rounds: one in June 2019 (midline of the new project) and one in December 2019. The end product will be a unique data set tracking child development from age 1-5 with children having received different intervention combinations in a randomized fashion.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 21/08/2018:
The following will be assessed at the midline (June 2019) and the endline (December 2019) (participants will be an average of 53 months of age at the midline, and 60 months of age at the endline):
1. Cognitive development assessed using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI):
2. School readiness, assessed using either or both of the following:
2.1. Daberon-II Screening for School Readiness test (DABERON-2)
2.2. School Readiness Instrument (SRI)

Previous primary outcome measures:
The following will be assessed at the midline (June 2019) and the endline (December 2019) (participants will be an average of 53 months of age at the midline, and 60 months of age at the endline):
1. Development of the following, assessed using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI):
1.1. Cognitive development
1.2. Executive function
1.3. Language development
2. Behavioural problems and prosocial behaviour, assessed from reports of mothers using the Strength and Difficulties Questionnaire (SDQ)
3. School readiness, assessed using either or both of the following:
3.1. Daberon-II Screening for School Readiness test (DABERON-2)
3.2. School Readiness Instrument (SRI)
4. Preschool quality, assessed using a self-developed Preschool Assessment Tool, based on the Early Childhood Education Quality Assessment Scale (ECEQAS), the Classroom Assessment Scoring System (CLASS) and the Teacher Instructional Practices and Processes System (TIPPS)

Key secondary outcome(s)
Current secondary outcome measures as of 21/08/2018:
The following will be assessed at the midline (June 2019) and the endline (December 2019) (participants will be an average of 53 months of age at the midline, and 60 months of age at the endline):
1 . Development of the following, measured using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI):
1.1 Executive function

1.2 Language Development
2. Behavioural problems and prosocial behaviour, assessed from reports of mothers using the Strength and Difficulties Questionnaire (SDQ)
3. Child anthropometric measures (height-for-age, weight-for-age and weight-for-height Z scores), used to assess the following using electronic weighing scales operated by trained data collectors:
3.1. Extent of growth faltering
3.2. Extent of growth recovery
4. Child rearing practices, assessed using UNICEF Family Care Indicators (FCIs) and subscales of the Home Observation for the Measurement of the Environment (HOME):
4.1. Level of stimulation in the home
4.2. Presence of toys and learning materials in the house
4.3. Parental involvement with the child
4.4. Child's routines
4.5. Organisation of the child's time inside and outside of the family house
5. Parental knowledge of child rearing practices, assessed using items from the Knowledge of Infant Development (KIDI) and a self-developed questionnaire designed to elicit maternal beliefs on the return to parental investment. As part of the previous trial we developed an instrument on eliciting maternal beliefs on the return to parental investment. This module gathers information on maternal beliefs which elicit their choices of investments in the development of their younger children. This questionnaire is designed to be filled in by the mother or the primary caregiver of the child. We present the primary caregiver some questions about a hypothetical child and ask her about the process of development of such child under different scenarios. The interviewer stressed that the hypothetical child was not the woman’s own child but a generic one, as such an approach made the description of the hypothetical scenarios easier. In terms of the scenarios, we present two groups of children, one who can speak easily and the other who find it harder to speak as well as two types of families, one family where the mother spends more time with the child and in another in which mother and child spend less time together.
5.1. Mother's knowledge of nutrition and stimulation
5.2. Mother's beliefs regarding importance of nutrition and stimulation for child development
6. Preschool quality, assessed using a self-developed Preschool Assessment Tool, based on the Early Childhood Education Quality Assessment Scale (ECEQAS), the Classroom Assessment Scoring System (CLASS) and the Teacher Instructional Practices and Processes System (TIPPS)

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3.1. Mother's knowledge of nutrition and stimulation
3.2. Mother's beliefs regarding important of nutrition and stimulation for child development

Completion date
16/07/2020

Eligibility

Key inclusion criteria
All children who were part of the primary sample for the initial trial (http://www.isrctn.com /ISRCTN18111205). This includes children aged 7-16 months and their families.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Months

Upper age limit
16 Months

Sex
All

Key exclusion criteria
Children not in the initial study (ISRCTN18111205).

Date of first enrolment
13/05/2018

Date of final enrolment

13/05/2018

Locations

Countries of recruitment
United Kingdom

India

Study participating centre
Pratham Education Foundation (Odisha head office)
Holding no.-1/N/5 Arundoya Nagar
Cuttack
United Kingdom
753012

Study participating centre
Pratham Education Foundation
At-Dahipur Po-Radhaballabhpur Soro
Balasore
United Kingdom
756045

Study participating centre
Pratham Education Foundation
At-Sapanpur PO-Sisua
Cuttack
United Kingdom
754202

Study participating centre
Pratham Education Foundation
At/Po- Puintala (Near Puintala block)
Balangir
United Kingdom
767071

Sponsor information

Organisation

Yale University

Organisation
Institute for Fiscal Studies

Organisation
Pratham Education Foundation-ASER Centre (India)

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

Organisation
University of Pennsylcania

Organisation
Yale University

ROR
https://ror.org/03v76x132

Funder(s)

Funder type
Not defined

Funder Name
Jacobs Foundation

Funder Name
World Bank Group

Alternative Name(s)
World Bank, The World Bank, Grupo Banco Mundial, Groupe Banque Mondiale, , Группа Всемирного банка, WBG

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United States of America

Funder Name
Economic and Social Research Council

Funder Name
European Research Council

Alternative Name(s)
The European Research Council, ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Dubai Cares

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date