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Early Childhood Development in the Slums of Cuttack, Odisha, India. A follow up

Submission date
27/02/2020

Recruitment status
No longer recruiting

Registration date
06/03/2020

Overall study status
Completed

Last Edited
01/04/2020

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
The importance of the first 5 years of life for long-term development is well-established. During this vital period, the development of children living in poverty is hindered by malnutrition, illness, and unstimulating home environments. Evidence shows that interventions in early childhood can be very important for psychological and social development. However, they are often delivered by experts and hence expensive and not feasible to expand widely.

Between 2013 and 2015, with the aim of promoting early childhood development and caregiver-child interactions in poor urban environments, a home-visiting programme was investigated (http://www.isrctn.com/ISRCTN89476603). The programme was cost-effective and was delivered by local women through weekly visits over 18 months in Cuttack, India. It was aimed at children aged 10-20 months and their mothers/primary caregivers. 54 slums were randomly allocated to receive the programme and 421 children and their families were invited to participate.

This programme involved structured play and other activities that the home visitor did with the caregiver and child during the visit but also encouraged the caregiver to continue with over the coming week, before the next visit. The home visitor would leave any materials required with the caregiver for that week, and most of the toys were made with locally available materials. The activities were all designed to be stimulating for the child and specific to improving one or more areas of child development. The programme was designed to increase the interactions between the caregiver and child even when not doing these specific play activities.

Children who received the intervention showed large positive impacts on child development after 18 months. On average, treated children experienced an increase in their learning skills and their ability to use language. These effects were larger for boys.

This study is a follow up of this group 6 years later to see if the positive impact of the home visiting programme can be sustained. This study also aims to see whether there have been positive effects of the programme on the development of the siblings of the children who were involved in the original study. Similarly, this study will investigate the differences between the study households who participated in the study and their neighbours who did not in terms of intrahousehold allocation of resources.

Who can participate?
Children and caregivers who participated in the original study and any siblings currently under the age of 16 can participate in this study. Neighbours of these families will also be invited to take part.

What does the study involve?
For the caregivers involved in the study, it will involve a number of questions and questionnaires in an interview with the study investigators about educational expenditure, time spent doing stimulating activities and household/family allocation of resources. For the children involved in the study, there will be assessments of learning skills and the ability to use language.

What are the possible benefits and risks of participating?
There are no risks for participating in the study. The administration of the child's assessment in which he/she plays some games appropriate for his/her age in front of a qualified person and in the presence of the primary caregiver or another adult member of the household does not pose any danger to children.

There are no direct benefits. Responses to this study will help to understand early childhood development.

Where is the study run from?
Trial study centre: Institute for Fiscal Studies (UK)
Trial site: Cuttack (India)

When is the study starting and how long is it expected to run for?
January 2019 to December 2020. Recruitment for the original study took place between November 2013 and December 2014 and has completed. Additional participants (the siblings and neighbours of those who participated in the original study) will be recruited between December 2019 and March 2020.

Who is funding the study?
Yale University (USA)

Who is the main contact?
Ms Lina Cardona
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Contact information

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Study information

Scientific Title
Impact evaluation of a psychosocial stimulation intervention on very young children living in urban poverty in India. A follow up

Acronym
ECD Cuttack follow up

Study objectives
A home visiting psychosocial stimulation intervention delivered when children were between 10 and 20 months old will have sustained effects on child development outcomes six years after the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/11/2019, UCL Research Ethics Committee (Office of the Vice Provost Research, 2 Taviton Street, University College London, London WC1E 6BT; +44 (0)20 7679 8717 ext. 28717; ethics@ucl.ac.uk), ref: 16727/001

Primary study design
Observational

Study design
Observational follow-up study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Early childhood development

Interventions
This is an observational follow-up study.

This is a follow-up to participants who were enrolled in a previous randomized control trial. Eligible participants were randomly allocated to receive the home visit intervention and were followed up at 1.5 years after the randomization. This study is inviting participants of the original study to respond to an interview 6 years after randomization. Some surveys will also be aimed at neighbours who consent to join the study. There will be no intervention or randomization this time.

For children aged 6 to 8 years, cognition and language will be assessed using an adapted version of the Wechsler Preschool and Primary Scale of Intelligence (WPPSI, Wechsler, 1967; Wechsler, 2002). Children's cognition will also be assessed through a set of tasks developed at the Spelke's lab at Harvard.

For children aged between 6 to 36 months, child cognition, language, and socioemotional development will be assessed using selected items from: The Caregiver Reported Early Development Instrument for assessing cognition, receptive language, expressive language, and socioemotional development; and the Bayley Scales of Infant Development III for assessing cognition, receptive language, and expressive language.

Intervention Type
Other

Primary outcome(s)
1. Cognitive and language development in children between 6 months and 3 years old assessed using the Bayley Scales of Infant Development III (Bayley-III) and the Caregiver Reported Early Childhood Instrument (CREDI) at 6 years after randomization in the initial study
2. Cognitive and language development in children between 4 and 16 years old assessed using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI-IV) and a set of tasks developed at the Spelke lab at Harvard University at 6 years

Key secondary outcome(s)
1. Quality of the home stimulation environment as measured by the 'play activities' and 'play materials' subscales of the Family Care Indicators in the home at 6 years
2. Maternal time spent on high stimulation activities with children in the home as measured by time use module in the household questionnaire at 6 years
3. Educational expenditure assessed through questions about educational expenditure in the previous month and year in the follow up interview at 6 years
4. Parental beliefs on returns to educational investment given different endowments assessed

in the follow up interview at 6 years
5. Intrahousehold allocation of resources given different levels of ability and health assessed in the follow up interview with families and their neighbors at 6 years

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Children who participated in the original study and their families
2. Siblings of participating children younger than 16 years old
3. Neighbours of participant households

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Upper age limit
16 Years

Sex
All

Key exclusion criteria
1. Mentally or physically disabled children
2. Children older than 16 years old

Date of first enrolment
16/12/2019

Date of final enrolment
05/03/2020

Locations

Countries of recruitment
United Kingdom

England

India

Study participating centre
Institute for Fiscal Studies
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Sponsor information

Organisation
Institute for Fiscal Studies

ROR
https://ror.org/04r1cjx59

Funder(s)

Funder type
University/education

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

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

Not provided at time of registration