

Impact evaluation of a psychosocial stimulation intervention on very young children living in urban poverty in India

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| Submission date 04/11/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 10/12/2013 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 01/04/2020 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

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 psychosocial development. However, they are often delivered by experts and hence expensive and not feasible to expand widely. We will implement and evaluate a cost-effective intervention – based on Grantham-McGregor’s curriculum and delivered by local women through weekly home visits over 18 months – targeted to children aged 10-20 months and their mothers/primary caregivers. The intervention aims to promote early child development and maternal-child interactions in a very poor urban environment.

Who can participate?

Children aged 10-20 months and their mothers/primary caregivers from the 54 slums in Cuttack, Odisha, India.

What does the study involve?

The 54 slums will be randomly allocated to either the intervention or the control group. The intervention group will receive weekly home visits lasting around one hour. The 'home visitors' will be local women and will follow the Grantham-McGregors curriculum and protocols specially adapted for the context of Odisha. They will interact with carers and children and will discuss the importance of stimulation and play for child development with the carer. The control group will receive no intervention. We will assess child development and conduct household and slum surveys before and after the intervention. We will also obtain detailed information on the quality of the home environment.

What are the possible benefits and risks of participating?

Benefits to participants include information on the child's development and also, within the intervention households, advice on how to improve child development. We do not foresee any risks for study participants.

Where is the study run from?
The Institute for Fiscal Studies (UK)

When is the study starting and how long is it expected to run for?
November 2014 to May 2015

Who is funding the study?
The study is funded by a gift from Mr Martin Rushton-Tuner and the Waterloo Foundation.

Who is the main contact?
Dr Marta Rubio-Codina (marta_r@ifs.org.uk)
Dr Britta Augsburg (brita_a@ifs.org.uk)

Contact information

Type(s)
Scientific

Contact name
Ms Safija Jusupovic

Contact details
Institute for Fiscal Studies
7 Ridgmount Street
London
United Kingdom
WC1E 7AE

Additional identifiers

Study information

Scientific Title
Early Childhood Development in the slums of Cuttack, Odisha, India

Acronym
ECD Cuttack

Study objectives
Child cognitive and language development will be improved by introducing a systematic psychosocial stimulation curriculum delivered weekly by local women (home visitors) aimed at promoting maternal-child interactions and the quality of the home environment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. IMFR, 27/06/2013, ref: IRB00007107; FWA00014616; IORG0005894
2. UCL Ethics Committee, Graduate School Office, 02/09/2013, ref: 2168/001

Study design

Two-arm cluster (slum) randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Early childhood development

Interventions

Slum-based intervention to promote early childhood development. 54 clusters in total will be randomised to either the intervention or the control group.

1. Intervention group: 27 clusters will receive psychosocial stimulation through weekly home visits - lasting around one hour - to mothers/primary carers of children aged 10-20 months. The 'home visitors' will be local women and will follow the Grantham-McGregors curriculum and protocols specially adapted for the context of Odisha. They will interact with carers and children and will discuss the importance of stimulation and play for child development with the carer.

2. Control group: 27 clusters will receive no intervention.

Total duration of intervention: 12 months (2 periods of 1 month of data collection will precede and follow the interventions)

Updated 25/11/2015:

Total duration of intervention: 18 months (2 periods of 1 month of data collection will precede and follow the interventions)

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Current primary outcome measures as of 25/11/2015:

Children's cognitive, receptive language, expressive language, and fine motor development (assessed using Bayley-III at follow-up).

Previous primary outcome measures:

Children's cognitive, language, motor and socio-emotional development (ASQ-3 test at baseline; Bayley-III at follow-up or DAS-II [TBC])

Key secondary outcome(s)

Current secondary outcome measures as of 25/11/2015:

1. Quality of the home stimulation environment (as measured by the 'play activities' and 'play materials' subscales of the Family Care Indicators) at baseline in the home; at follow-up in the assessment centre and in the home

2. Maternal time spent on high stimulation activities with children (as measured by time use module in household questionnaire) both at baseline and at follow-up in the home
3. Mother's knowledge of child development (as measured by a subset of selected items from the KIDI instrument) both at baseline and at follow-up in the home

Previous secondary outcome measures:

1. Children's height, weight and morbidity (standard WHO methods and definitions -- height and weight will only be collected at baseline)
2. Quality of the home environment: play activities and play materials (FCI instrument -- baseline and follow-up)
3. Maternal depressive symptoms (FCI questions from CES-D -- baseline and follow-up)
4. Maternal and household socio-economic characteristics (household survey -- baseline and follow-up)

Completion date

31/03/2016

Eligibility

Key inclusion criteria

1. Children aged 10-20 months from the 54 slums in Cuttack, Odisha, India
2. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 months

Upper age limit

20 months

Sex

All

Total final enrolment

421

Key exclusion criteria

1. Children outside the 10-20 month age range
2. Mentally or physically disabled children
3. Children born as twins

Date of first enrolment

11/11/2013

Date of final enrolment

15/12/2014

Locations

Countries of recruitment

United Kingdom

England

India

Study participating centre

Institute for Fiscal Studies

London

United Kingdom

WC1E 7AE

Sponsor information

Organisation

Institute for Fiscal Studies (UK)

ROR

<https://ror.org/04r1cjx59>

Funder(s)

Funder type

Charity

Funder Name

Gift from Mr Martin Rushton-Turner (UK)

Funder Name

The Waterloo Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/06/2020 | 06/12/2019 | Yes | No |