

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

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-McGregor's 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)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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])

Secondary outcome measures

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)

Overall study start date

12/08/2013

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

Age group

Child

Lower age limit

10 Months

Upper age limit

20 Months

Sex

Both

Target number of participants

400 children and their mothers/caregivers in 54 slums (27 treatment, 27 control)

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**

England

India

United Kingdom

Study participating centre

Institute for Fiscal Studies

London

United Kingdom

WC1E 7AE

Sponsor information

Organisation

Institute for Fiscal Studies (UK)

Sponsor details

7 Ridgmount Street
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United Kingdom
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Sponsor type

Research organisation

Website

<http://www.ifs.org.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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