

Early Childhood Development: Identifying successful interventions and the mechanisms behind them

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Registration date 18/12/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/10/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

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: A cluster-randomised controlled trial to Identify successful interventions and the mechanisms behind them

Acronym

ECD

Study objectives

The importance of the first 5 years of life for long-term development is well-established. During this vital period many children - particularly in developing countries - are surrounded by poverty, and do not receive adequate physical, mental or emotional nourishment. As adults they are likely to be at a disadvantage in terms of their education levels and health, to have high fertility rates, and to provide inadequate stimulation and resources for their own children, thus contributing to the intergenerational transmission of poverty and to economic inequality.

There is increasing evidence that interventions in early childhood are very important for physiological and psychological development. However, if - as is often the case - they are implemented by experts who live outside the communities, they are both expensive and infeasible to expand widely. In this research we aim to develop and evaluate a cost-effective and sustainable intervention to promote early child development. The intervention will be implemented using local community resources, thus providing a viable model for scaling up if successful. Our setting is Colombia.

To evaluate the intervention, some communities will be chosen randomly to receive it, others not. Surveys will be conducted twice - before the intervention starts, and 18 months later when it ends. The main outcomes we will measure are the childrens motor, cognitive and socio-emotional development, and their health. To this end, we will administer Bayleys tests to children before and after the intervention, as well as collect detailed data on their health status. We will also obtain detailed information on various socio-economic characteristics of the household, in order to be able to understand the constraints that poor households face when making choices relevant to their children's development, and ultimately to investigate why the intervention works or not.

Ethics approval required

Old ethics approval format

Ethics approval(s)

UCL Research Ethics Committee, 28/01/2009, ref: 1827/001

Study design

Four-arm cluster randomised controlled parallel group 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 interventions in developing countries, nutritional supplementation; psychosocial stimulation

Interventions

Community-based intervention to promote early childhood development. 96 clusters in total.

1. Stimulation group

24 clusters will receive stimulation through weekly home visits - lasting around one hour - to mothers/primary carers of children aged between 12 and 24 months, for a period of 18 months. The home visitors will interact with carers and children and will discuss the importance of psychosocial stimulation for child development with the carer. The home visitors will be drawn from local female elected representatives, and will receive extensive guidance and preparation for their role.

2. Nutrition group

24 clusters will receive micronutrients in the form of 'Nutritional Anemia Formulation Sprinkles' to children between 12 and 24 months at the start of the study, also for a duration of 18 months. Sprinkles are sachets containing a blend of micronutrients in powder form, which are easily sprinkled onto foods prepared in the home. Any homemade food can be instantly fortified by adding Sprinkles. Coating of the iron prevents changes to the taste, colour or texture of the food to which Sprinkles are added. Sprinkles were developed by the Sprinkles Global Health Initiative to prevent and treat micronutrient deficiencies among young children and other vulnerable groups at risk.

3. Stimulation and nutrition group

24 clusters will receive both home visits and Sprinkles. This set up will allow us to test whether the intervention is more likely to be successful if childrens nutrition is also targeted - an important ongoing debate.

4. Control group

24 clusters will receive no intervention.

Total duration of interventions: 18 months (2 periods of 3 months of data collection will precede and follow the interventions)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Childrens motor and mental development measured using the Bayley Scales of Infant and Toddler Development, third edition.
2. Childrens nutritional status, measured by collecting height and weight, haemoglobin levels (using capillary blood specimens from finger prick samples), and childrens consumption of iron rich food

Secondary outcome measures

1. Maternal depression measured using the 10-item CESD Scale.
2. Investigate the constraints that poor households face when making choices relevant to their children's development, and ultimately to investigate why the intervention works or not. We will do this by building a structural model using detailed socio-economic data at the household level.

Overall study start date

01/01/2010

Completion date

30/11/2011

Eligibility

Key inclusion criteria

1. Households eligible for the Colombian conditional cash transfer program 'Familias en Accion'
2. Aged between 12 and 24 months
3. Informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

12 Months

Upper age limit

24 Months

Sex

Both

Target number of participants

1500 (96 clusters, with 24 clusters in each treatment arm)

Key exclusion criteria

1. Children outside the 12-24 month age range at the start of the intervention
2. Children with serious congenital abnormalities
3. Twins

Date of first enrolment

01/01/2010

Date of final enrolment

30/11/2011

Locations

Countries of recruitment

Colombia

England

United Kingdom

Study participating centre

Institute for Fiscal Studies

London

United Kingdom

WC1E 7AE

Sponsor information

Organisation

Economic and Social Research Council (ESRC) (UK)

Sponsor details

Polaris House

North Star Avenue

Swindon

United Kingdom

SN2 1UJ

Sponsor type

Research council

Website

<http://www.esrc.ac.uk>

ROR

<https://ror.org/03n0ht308>

Funder(s)

Funder type

Research council

Funder Name

Economic and Social Research Council (ESRC) (UK)

Alternative Name(s)

ESRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Inter-American Development Bank (International)

Alternative Name(s)

Banco Interamericano de Desarrollo, Banco Interamericano de Desenvolvimento, Banque Interaméricaine de Développement, IADB, BID, IDB

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United States of America

Funder Name

International Growth Centre (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	29/09/2014		Yes	No