

An integrated Early Childhood Development intervention targeted at young children attending FAMI Centres in Colombia

Submission date 13/10/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/10/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The first 5 years of a child's life are very important. It is a time of dramatic brain growth and development. However, this vital time of development can be badly affected by malnutrition, illness and living in an unstimulating home environment. There is evidence to suggest that interventions in early childhood can have a significant effect on children's development. Our focus is rural and semi-urban Colombia where the development of children lags behind their urban counterparts, and where the quality of early childhood services is poor and inadequate. In 2011, the government launched a national early childhood strategy From Birth to 5/Forever with the aim to improve childcare services provided to about 1.2 million children. However, the strategy has a lower capacity in rural and semi-rural areas than in urban areas. This project will design, implement and evaluate improvements to the curriculum used in the existing early childhood services in rural and semi-urban areas, the Hogares Fami (FAMI). FAMI are family-based parenting services for pregnant women and children below 24-30 months. The aim is to improve child development by improving parenting practices.

Who can participate?

Children aged between 0-12 months of age and their mothers, and also pregnant women who are attending FAMIs in towns in rural and semi-urban Colombia. FAMI is a programme working with women and children offering support on, for example, self-care during pregnancy and parental skills.

What does the study involve?

Each town is randomly allocated to either the treatment or the control group. FAMIs in control towns operate as usual. Treatment towns operate new enhanced FAMIs where all the participants in that town follow a structured psychosocial stimulation curriculum for 18 months, promoting child development through play, language activities, and improved parenting. The intervention also includes a food basket, which is delivered monthly through the FAMI mothers. Data is collected before the study begins and when it ends.

What are the possible benefits and risks of participating?

No risks are foreseen for study participants.

Where is the study run from?

The study is run from Bogota and Medellin (Colombia), and from London (UK).

When is the study starting and how long is it expected to run for?

September 2014 to April 2016

Who is funding the study?

1. Grand Challenges (Canada)
2. Success Foundation (Fundación Éxito) (Colombia)

Who is the main contact?

Prof. Raquel Bernal Salazar

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

An integrated Early Childhood Development intervention targeted at deprived young children in Colombia: a randomised controlled trial evaluation

Study objectives

Promote child development through improved parenting practices for children 0-30 months of age attending family-based parenting services, FAMI, in rural and semi-urban areas of Colombia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Committee on Research Ethics, University of Los Andes, 08/05/2014, ref: 287 de 2014
2. UCL Research Ethics Committee, 16/07/2014, ref: 2168/011

Study design

Two-arm cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Early childhood development (ECD); psychosocial stimulation

Interventions

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

1. Treatment group: enhanced FAMI through psychosocial stimulation and nutrition curriculum.

FAMIs in 49 clusters will receive an enhanced FAMI intervention where all children (0-24 months) attending FAMI, their mothers, and pregnant women in the FAMI will follow a structured psychosocial stimulation curriculum, focused on the promotion of child development through play, language activities, and messages on child stimulation and parenting. The curriculum will also include best nutritional practices. This curriculum will be delivered by (current/existing) FAMI mothers in weekly group sessions and monthly home visits following the standard modus operandi at regular FAMIs for 18 months. Since February 2015, the intervention will also include a food basket (delivered monthly through the FAMI mothers) (added 01/12/2015). Note that we will only evaluate children 0-12 months old in the FAMI, and their mothers, and pregnant women.

2. (Active) Control group: regular FAMI

Pregnant women, and children and their mothers in 47 clusters will receive the standard FAMI program, as is currently operating in these areas.

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

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Current primary outcome measures as of 18/04/2017:

1. Children's cognitive, receptive and expressive language and motor development, measured using the Bayley-III at follow-up (April-July 2016)
2. Children's socio emotional development, measured by ASQ test at follow-up (April-July 2016)
3. Children's height and weight, measured by assistant nurses in local community centers at baseline (August-November 2014) and follow-up (April-July 2016)
4. WHO motor milestones (the latter for children 6-12 months only), measured at baseline (August-November 2014)

Previous primary outcome measures:

1. Children's cognitive, language, motor and socio-emotional development (possibly using the ASQ test, the MacArthur-Bates Child Development Inventories, and/or the Bayley-III), measured at follow up
2. Height and weight, measured at baseline and follow up (added 24/11/2015)
3. WHO motor milestones (the latter for children 6-12 months only), measured at baseline

Secondary outcome measures

Current secondary outcome measures as of 18/04/2017:

Measured at baseline (August-November 2014) and follow-up (April-July 2016):

1. Parenting practices and the level of stimulation in the home, measured using UNICEF's Family Care Indicators (FCI)
 - 1.1. No. of toy sources
 - 1.2. No. of varieties of play materials
 - 1.3. No. of varieties of play activities over past 3 days
 - 1.4. No. of parental care activities over past 3 days
2. Use of verbal or physical abuse in the household, measured using UNICEF's FCI
3. Parent knowledge about early childhood development, measured using a 10-item scale based on KIDI

4. Maternal self-efficacy, measured using the Caregiver Role Test – Modified
5. Mothers with depression symptoms, measured using Center for Epidemiologic Studies Depression Scale (CESD-10)
6. Maternal social support, measured using the DUKE UNC-11 scale
7. Variables of FAMI providers: activities developed in group sessions, collected through videos that are coded

Previous secondary outcome measures:

1. Parenting practices and the level of stimulation in the home, possibly using the Family Care Indicators (FCI)
2. Activities developed by FAMI providers and knowledge of FAMI mothers on child rearing and development

Overall study start date

01/02/2014

Completion date

01/07/2016

Eligibility

Key inclusion criteria

1. Children aged 0-12 months of age at baseline, attending FAMIs in 96 towns in rural and semi urban Colombia, by random assignment within the FAMI (preference will be given to children 0-6 months so that they can benefit from the intervention longer)
2. Pregnant women at baseline in the same FAMIs, by random assignment within the FAMI
3. Informed consent

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

2,000 children in 96 clusters, 1,200 pregnant women in 96 clusters

Key exclusion criteria

1. Children outside the 0-12 months of age range at baseline attending selected FAMIs (these children will be excluded from the study but will receive the intervention)
2. Children and pregnant women not attending selected FAMIs

Date of first enrolment

01/09/2014

Date of final enrolment

31/03/2016

Locations

Countries of recruitment

Colombia

England

United Kingdom

Study participating centre

Universidad de los Andes

Bogota

Colombia

N/A

Study participating centre

Institute for Fiscal Studies

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Sponsor information

Organisation

Grand Challenges Canada (Canada)

Sponsor details

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Sponsor type

Government

ROR

<https://ror.org/02snbhr24>

Funder(s)

Funder type

Other

Funder Name

Grand Challenges Canada-- 0642-03-10

Alternative Name(s)

Grands Défis Canada, GCC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

Success Foundation (Fundación Éxito) (Colombia)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal in first quarter 2018.

Intention to publish date

31/03/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Raquel Bernal.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/04/2017	28/04/2017	No	No
Basic results		09/10/2018	09/10/2018	No	No