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# Enhancing early child development in Brazil through support for positive parenting

**Submission date**
20/09/2016

**Recruitment status**
No longer recruiting

**Registration date**
22/10/2016

**Overall study status**
Completed

**Last Edited**
18/01/2019

**Condition category**
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Poverty has harmful effects on early child development, with long-term consequences for educational and health outcomes. Public health interventions have tried to enhance early child development by improving the quality of children's early experiences, both in the home and in child care settings. A key focus of these programs has been to encourage high-quality language interactions by promoting reading aloud between parents and children. Many such programs have been shown to enhance children's educational and health outcomes among low-income families in the United States. However, there has been limited study of such programs in low- and middle-income countries. It is also not known whether the addition of parenting programs to educational programs applied by teachers in child care settings provide additional benefits to child development. This study takes place in two parts. The first part of this study aims to find out whether adding a parenting program to an educational childcare program can improve parenting, early child development and performance in school. The second part of this study aims to compare children in educational childcare centers will be compared with similar children who are not attending childcare in terms of child development and performance in school.

Who can participate?
In the first part of the study, children aged 1-6 who attend an educational childcare facility and one of their parents can take part. In the second part of the study children aged 1-6 who do not attend an educational childcare facility and one of their parents can take part.

What does the study involve?
In the first part of the study, participating childcare centres are randomly allocated to one of two groups. In the first group, children receive educational childcare as usual and parents take part in a parenting program. This involves workshops for parents that provide educational support for reading aloud, play and other opportunities for interacting with children, and a book-loan program in which parents will be able to borrow children's books to take home and then exchange them for new ones on a regular basis. The workshops are designed to take place during regular parent-teacher meetings, typically once every month or once every two months. In the second group, children receive educational childcare as normal only. At the start of the study and then after 6-12 and 18-24 months, parents complete a range of questionnaires to assess their parenting and children have their development assessed in terms of language,

cognition (thinking and memory) and social/emotional skills.
In the second part of the study, participants complete the same assessments as those in part one of the study at the start and then after 6-12 and 18-24 months but continue with their lives as normal throughout (children not attending educational childcare).

What are the possible benefits and risks of participating?
There may be no direct benefits for participating families. However, it is possible that participants receiving the parenting program will have enhancements in their children's development, and that parents will learn about their child's development by participating in the assessments. There are no notable risks involved with participating

Where is the study run from?
Família que Acolhe (Brazil)

When is the study starting and how long is it expected to run for?
November 2015 to December 2021

Who is funding the study?
Instituto Alfa e Beto (Brazil)

Who is the main contact?
Dr Alan Mendelsohn
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# Contact information

### Type(s)
Public

### Contact name
Dr Alan Mendelsohn

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

S14-00602

# Study information

## Scientific Title
Enhancing early child development in low-income families in Brazil through support for positive parenting: A cluster randomized contolled trial in educational child care settings

## Study objectives
Part 1:
Addition of a positive parenting component to an educational childcare program will result in enhanced parenting, early child development and school readiness among low-income families in a moderately sized city in Brazil.

Part 2:
Children participating in educational child care will have enhanced early child development and school readiness compared to children who have not done so.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Ethics Committee of the Pontificia Universidade Catolica do Rio Grande do Sul, 16/10/2014, ref: 00005830
2. Institutional Review Board of New York University School of Medicine, 09/02/2015, ref: 00004952

## Study design
Part 1:
Single-blind cluster randomised controlled trial

Part 2:
Observational cohort study

## Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
Other

## Study type(s)
Other

## 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
Child development

## Interventions
Part 1:
Each educational child care center is randomized to one of two groups using a random number generated through Microsoft Excel. Co-located sites (i.e., educational child care centers at the same street address) are randomized in blocks to avoid contamination.

Intervention group: Centres receive a positive parenting program delivered as an add-on to standard educational child-care. This program includes workshops for parents that provide educational support for reading aloud, play and other opportunities for interacting with children, and a book-loan program in which parents will be able to borrow children's books to take home and then exchange them for new ones on a regular basis. The positive parenting workshops are designed to take place during regular parent-teacher meetings, typically once every month or once every two months.

Control group: Centres receive standard educational child care without addition of the parenting program

All participants are followed up after 6-12 months and 18-24 months.

Part 2:
Participants in the cohort enrolled for Part 2 of the study receive assessments only, according to the same schedule as those enrolled in part 1. All outcome measures are collected at baseline, 6-12 and 18-24 months.

## Intervention Type
Behavioural

## Primary outcome measure
Part 1 and 2:
All outcome measures are collected at baseline, 6-12 and 18-24 months

Parenting outcomes:
1. Parenting is assessed using:
1.1. Cognitive stimulation in the home / Reading attitudes and activities: Survey instruments will include the StimQ and an adapted version of the Reading Beliefs Inventory
1.2. Videotaped parent-child interactions while reading, to be coded with a system such as the Adult/Child Interactive Reading Inventory (ACIRI)

Child Development outcomes:
1. Language and emergent literacy is assessed using:
1.1. A Brazilian Portuguese adaptation of the Peabody Picture Vocabulary Test and the Expressive One-Word Picture Vocabulary Test, developed and validated by Capovilla and Seabra.
1.2. Naturalistic language samples
1.3. Word and non-word repetition tasks
1.4. A Brazilian Portuguese test for assessing children's early literacy abilities (e.g., letter knowledge, letter sounds, rhyming, blending, segmentation), developed by Seabra
2. Cognition is assessed using:
2.1. Age-specific parent-completed developmental questionnaires called Ages & Stages (ASQ)

2.2. The Snijders-Oomen nonverbal intelligence test (SON-test)
2.3. Verbal and non-verbal working memory using protocols developed by Seabra and colleagues
3. Social-emotional development is measured using:
3.1. Select items from the Child Behavior Checklist (CBCL, parent report)
3.2. Select subscales from the Infant-Toddler Social and Emotional Assessment-Revised (ITSEA)
3.3. Preschool Self-Regulation Assessment Assessor Report (PSRA)

### Secondary outcome measures
Part 1 and 2:
All outcome measures are collected at baseline, 6-12 and 18-24 months
1. Parental stress related to interactions with child is assessed using the PSI Short form and Parent-Child Dysfunctional Interactions Subscale
2. Parenting self-efficacy is assessed using an adapted version of the Karitane Parenting Self Confidence Scale (KPSC)
3. Exposure to electronic media is assessed through information provided by parents about amount of electronic media (e.g. television, videos) to which their children are exposed
4. Maternal depressive symptoms are assessed using the Edinburgh Postnatal Depression Scale (EPDS)
5. Parental self-sufficiency
6. Child health is measured by assessing nutritional status through parent interview and from review of Educational Center records (part 1) and parent interviews (part 2)

### Overall study start date
01/11/2015

### Completion date
31/12/2021

## Eligibility

### Key inclusion criteria
Part 1:
1. Parent-child dyads participating in educational child care centers
2. Children aged between 1-6 years

Part 2:
1. Parent-child dyads from communities with comparable characteristics to those in part 1
2. Children aged between 1-6 years
3. Children not attending an educational child care center

### Participant type(s)
Mixed

### Age group
Mixed

### Sex
Both

### Target number of participants

1200 parent-child dyads (1200 parents and 1200 children). For Part 1 (cluster RCT), parent-child dyads will be enrolled from 22 -30 centers, with approximately 20-30 dyads per center. 400 parent-child dyads will be recruited for part 2

### Key exclusion criteria
Known significant medical/neurologic conditions likely to influence development (e.g. significant genetic abnormality, significant chronic disease).

### Date of first enrolment
01/11/2015

### Date of final enrolment
31/12/2018

## Locations

### Countries of recruitment
Brazil

### Study participating centre
**Família que Acolhe**
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## Sponsor information

### Organisation
New York University School of Medicine

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145 East 32nd Street
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### Sponsor type
University/education

### Organisation
Instituto Alfa e Beto

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SQS Quadra 04 Bloco A
N. 209 sala 303- Edifício Mineiro
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Brazil
70304

### Sponsor type
Other

### Website
http://www.alfaebeto.org.br/

### Organisation
New York University School of Medicine

### Sponsor details

### Sponsor type
Not defined

### Website
http://www.med.nyu.edu/

## Funder(s)

### Funder type
Other

### Funder Name
Instituto Alfa e Beto

## Results and Publications

### Publication and dissemination plan
Planned publication of findings in a high-impact peer reviewed journal around one year completion of the first follow-up 6 to 12 months after enrollment.

### Intention to publish date
31/12/2019

### Individual participant data (IPD) sharing plan

Ethics/IRB approval to make available participant level data has not been obtained. Data will be held in a secure server hosted by NYU School of Medicine and will be shared with researchers or regulatory agencies upon request.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2018 | | Yes | No |