

# Evaluating a language intervention for children in inner city schools in Brazil

<b>Submission date</b> 28/07/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/08/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/02/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Language skills are the cornerstone of education: they underpin literacy and numeracy, promote social interaction and are associated with better self-regulation. It follows that poor educational outcomes are very likely for children with poorly developed spoken language. This is particularly true for those born into socially disadvantaged communities. Early education intervention programmes can help to support these children but there is little research regarding the social and cultural factors that promote the success of such interventions. This study will test a language intervention program in a group of schools in the Sao Paulo area of Brazil. The aim is to identify factors that can help to promote successful language development.

### Who can participate?

Children (first grade, aged 6-8 years) in one classroom from each of 20-27 schools in the municipality of Santo Andre (an area of Sao Paulo)

### What does the study involve?

Half of the schools will be allocated to the treatment group and half to the control group. Children at the treatment group schools will receive 40 minutes of targeted support per day, 4 days a week, for 20 weeks to help develop their speaking and listening, vocabulary and storytelling skills. Children at the control group schools will not receive these lessons but will continue to have language lessons as normal.

### What are the possible benefits and risks of participating?

It is anticipated that the additional lessons will help to support the language development of the children in the treatment group. This is the main benefit of participation. In terms of risk, participants may become tired during the intervention sessions but the time commitment does not extend the normal school day. Participating children will also be asked to complete a test battery before and after the intervention which will take about 1 hour to complete. The tests have been designed and normalized within the appropriate age range and have clear stop rules which limit the number of items for children at the lower ends of the ranges. The researchers do not anticipate that they will cause anxiety for the children but children do not need to complete the testing in order to receive the intervention programme.

Where is the study run from?  
Federal University of São Paulo (Brazil)

When is the study starting and how long is it expected to run for?  
October 2020 to July 2022

Who is funding the study?  
British Academy (UK)

Who is the main contact?  
1. Dianne Newbury, diannenewbury@brookes.ac.uk  
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## Contact information

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Public

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

ECE190048

## Study information

### Scientific Title

The Programa Educacional para a Promoção da Linguagem Infantil (Educational Program for Promoting Child Language) Intervention Trial (PROLIN)

### Acronym

PROLIN

### Study objectives

Children receiving a language intervention (the treatment group) will make significant advances in language skills compared with children who do not receive the intervention (the control group).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Approved 27/03/2020, Ethics Committee of the Universidade Federal de São Paulo (Rua Botucatu, n.º 740 - Vila Clementino - São Paulo - SP - CEP: 04023-900, Brazil; +55 (0)11 5571-1062, +55 (0)11 5539-7162; cep@unifesp.br), ref: CAAE: 29401920.8.0000.5505; Registration No: 3.903.532
2. Approved 17/09/2020, Oxford Brookes University Faculty of Health and Life Sciences University Research Ethics Committee (UREC, SNC G.19, Headington Campus, Oxford Brookes University, Oxford, OX3 0BP, UK; Tel: not available; adamwhite@brookes.ac.uk), ref: 201385

### Study design

Cluster randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Cluster randomised trial

### **Study setting(s)**

School

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format. Please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Language and reading development

### **Interventions**

The study will include 20-27 schools (600-800 children aged 6-8) from inner-city schools in Sao Paulo and will be teacher-led. Schools will be allocated to the treatment or control groups through simple randomisation using the website <https://www.random.org>.

Classes in the schools allocated to the treatment group will receive 80 intervention sessions over 20-30 weeks. Sessions will be teacher-led, in class groups and will last 30-40-minutes. Intervention sessions will comprise: 1) active listening, supported by multi-sensory activities involving phonological awareness; and 2) vocabulary and narrative, supported by reading books. Each class will receive four sessions per week.

Classes in the control group will receive business as normal during the intervention time.

All children in participating classrooms will undergo language assessment at pre-test (August 2021).

Language will be assessed before the intervention using four measures of language ability. These four measures will be used as indicators of a latent variable to form the primary outcome measure.

1. Expressive vocabulary (picture-naming task, standardised and taught)
2. Receptive vocabulary (picture-matching task)
3. Sentence repetition
4. Listening comprehension (short audio-presented story and questions)

In addition to language, phonological awareness will be assessed before the intervention with the following four measures. These are experimental measures that will be used as indicators of a latent variable to form one of the secondary outcomes.

5. Syllable segmentation and identification
6. Rhyme identification and retrieval
7. Initial phoneme identification
8. Final phoneme identification

The same battery of eight tests will be applied at mid-test (Christmas 2021).

At post-test (February 2021), the researchers will use these eight measures supplemented by three additional measures; a measure of language ability and two measures of early reading

skills:

9. Expressive language (language test - short visual scene. Child must describe and answer questions)
10. Letter naming (reading test)
11. Single-word reading (reading test)

Efficacy will be assessed by comparing intervention and control groups pre-, mid- and post-intervention. Analyses will be based on latent variable ANCOVA models implemented in an SEM framework. The primary outcome variable is language ability, measured by a latent variable with loadings from: expressive vocabulary, receptive vocabulary, sentence repetition, and listening comprehension (tests 1-4 above). This latent variable will be constructed from identical measures administered at pre-test, mid-test and post-test. The pre-test latent variable will be the covariate, and the post-test latent variable the outcome measure. The effects of the intervention will be measured by the y-standardised regression coefficient for a group dummy variable. The effects of clustering within schools will be accounted for by using robust (Huber-White) cluster standard errors.

Three secondary outcome measures will be considered: phonological awareness, early literacy and an additional measure of expressive language.

Phonological awareness will be measured by a latent variable with loadings from syllable segmentation and identification, rhyme identification and retrieval, initial phoneme identification and final phoneme identification (tests 5-8 above).

Early literacy will be measured by a latent variable with loadings from letter knowledge and word reading (tests 10 and 11 above) assessed at post-test only.

The researchers will also use the measure of expressive language (test 9 above, administered at post-test only) as an additional secondary outcome measure.

The analysis plan for each secondary outcome will be identical to that for the primary outcome detailed above except that the covariate in this case will be the language pre-test latent variable. For the measure of expressive language (test 9 above) the researchers will conduct a latent variable ANCOVA model with the pretest language latent variable as the covariate with measurement error being accounted for by constructing a latent variable where the error variance of the expressive language variable is estimated from the reliability of the measure. The effects of the intervention in each of these models will be measured by the y-standardised regression coefficient for a group dummy variable. The effects of clustering within schools will be accounted for by using robust (Huber-White) cluster standard errors.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Language ability is measured with a latent variable which depends on the four measures below, each taken at baseline (0 weeks), mid-term (week 14) and post-test (week 20):

1. Expressive vocabulary (50-item picture-naming task, standardised and taught)
2. Receptive vocabulary (25-item picture-matching task)
3. Sentence repetition (15 items)
4. Listening comprehension (three short audio-presented stories and 15 questions)

## **Secondary outcome measures**

1. Phonology is measured with a latent variable which depends on the four measures below, each taken at baseline (0 weeks), mid-term (week 14) and post-test (week 20):

- 1.1. Syllable segmentation and identification (8 items)

- 1.2. Rhyme identification and retrieval (8 items)
- 1.3. Initial phoneme identification (5 items)
- 1.4. Final phoneme identification (5 items)
- 2. Reading skills are measured with a latent variable that depends upon three measures, each measured at post-test (20 weeks):
  - 2.1. Expressive language (short visual scene. Child must describe and answer questions, similar to the Renfrew Action Picture Test)
  - 2.2. Letter naming (reading test, 32 items)
  - 2.3. Single-word reading (reading test, 14 items)

**Overall study start date**

01/10/2020

**Completion date**

01/07/2022

## **Eligibility**

**Key inclusion criteria**

Participating classrooms will be identified through contact with the school administrators. All children within the participating classroom will be invited to participate without exception.

**Participant type(s)**

Learner/student

**Age group**

Child

**Sex**

Both

**Target number of participants**

650

**Total final enrolment**

403

**Key exclusion criteria**

All children within the participating classroom will be invited to participate without exception

**Date of first enrolment**

17/08/2021

**Date of final enrolment**

31/08/2021

## **Locations**

**Countries of recruitment**

Brazil

**Study participating centre**

**Child Centres of Education from the municipality of Santo André**

c/o Universidade Federal de São Paulo

R. Botucatu, 802

Vila Clementino - SP

São Paulo

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## **Sponsor information**

**Organisation**

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**Sponsor type**

University/education

**Website**

<https://www.brookes.ac.uk/>

**ROR**

<https://ror.org/04v2twj65>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

British Academy

**Alternative Name(s)**

The British Academy

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Results of the study will be published in a peer-reviewed scientific journal at the end of the trial. Protocols for analysis will be provided as part of resultant publications.

**Intention to publish date**

01/01/2025

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other