ISRCTN11938488 https://doi.org/10.1186/ISRCTN11938488

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

Submission date
28/07/2021

Recruitment status
No longer recruiting

Registration date
13/08/2021

Overall study status
Completed

Last Edited
20/02/2024

Condition category
Other

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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)

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Child

Sex
All

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
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Sponsor information

Organisation
Oxford Brookes University

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
University/education

Funder Name
British Academy

Alternative Name(s)
BA British Academy, The British Academy, BA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes