ISRCTN13436925 https://doi.org/10.1186/ISRCTN13436925

The effectiveness of an adapted Nuffield Early Language Intervention programme in Paraguayan school children

Submission date
18/05/2025

Recruitment status
No longer recruiting

Registration date
19/05/2025

Overall study status
Completed

Last Edited
19/05/2025

Condition category
Mental and Behavioural Disorders

[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
This study will evaluate the effectiveness of Programa NELI, an adaptation of the Nuffield Early Language Intervention, a 20-week educational intervention programme suitable for children in Jardin Escolar and Pre-school (aged between 4-9 years) in Paraguayan public primary schools. The programme is designed to improve children's language skills, including those with language learning weaknesses. It is delivered by children's regular teachers who are specially trained to work with children individually and in small groups. Evidence from previous NELI studies has shown that the programme improves children's language skills. The current study uses a contextualised version of the programme to seek more robust evidence, from a larger sample, for the effectiveness of the programme.

Who can participate?
Children in Jardin Escolar and Pre-School classes (aged between 4-9 years) in Paraguayan primary schools.

What does the study involve?
Before the intervention programme begins, the language skills of all children in all participating classrooms will be assessed with the LanguageScreen app. Before randomised allocation of schools took place, schools were stratified based on three variables: (1) location (urban vs. rural), (2) technology (high-tech vs low-tech), and (3) size (big vs small). All children in each participating intervention school will receive the programme for 20 weeks from March to July 2025. Children in the waiting list control group will receive the intervention from July to November 2025. Once the intervention group have completed the 20-week programme, all children in every participating class will be assessed again using the same assessments. The language skills of children in the intervention group will be compared to those in the waiting list control group to see how much the children who received the intervention have improved as a result.

What are the possible benefits and risks of participating?
Children taking part in the intervention will benefit from additional small-group and individual teaching sessions. All children in each class identified through the whole-class screening as

having language weaknesses will receive the intervention. There are no anticipated risks of participation.

Where is the study run from?
Oxford Education and Assessment Ltd (UK)

When is the study starting and how long is it expected to run for?
March 2025 to November 2025

Who is funding the study?
Ministry of Education and Science (Paraguay)

Who is the main contact?
Prof. Charles Hulme, charles@oxedandassessment.com

Contact information

Type(s)
Principal investigator

Contact name
Prof Charles Hulme

ORCID ID
https://orcid.org/0000-0001-9499-5958

Contact details
3 Cartwright Way
Bardon Hill
Coalville
United Kingdom
LE67 1UB
-
charles@oxedandassessment.com

Type(s)
Scientific

Contact name
Dr Ernesto Roque Gutierrez

ORCID ID
https://orcid.org/0000-0002-3322-6343

Contact details
3 Cartwright Way
Bardon Hill
Coalville
United Kingdom

LE67 1UB
-
ernesto@oxedandassessment.com

Type(s)
Public

Contact name
Ms Mariela Rios Diaz

Contact details
3 Cartwright Way, Bardon Hill
Coalville
United Kingdom
LE67 1UB
-
mariela@oxedandassessment.com

Additional identifiers

Protocol serial number
PY-NELI-2025

Study information

Scientific Title
The effectiveness of an adapted Nuffield Early Language Intervention programme in promoting Paraguayan children's oral language

Acronym
PY-NELI

Study objectives
The researchers expect the PY-NELI programme to produce improvements in children's oral language skills

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/05/2025, OxEd & Assessment Ethics Committee (Unit 3, Cartwright Way, Bardon Hill, Coalville, LE67 1UE, United Kingdom; -; linda.mcdowell@geog.ox.ac.uk), ref: OXED_PY_2025_01

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Children with language difficulties

Interventions
Schools have been recruited from all across Paraguay. All children in all participating classrooms will undergo language assessments at pretest.

Randomisation:
From a population of 1,281 schools, we formed a control group of 281 schools, ensuring balance across three key variables: (1) location (urban vs. rural), (2) technology (high-tech vs low-tech), and (3) size (big vs small). First, each school was categorised by whether it was urban or rural, whether it possessed both internet and devices (high-tech) or not (low-tech), and whether its enrolment fell above or below the median (big vs small). These factors yielded strata that captured all combinations of the three variables. Next, we calculated the proportional representation of each stratum in the full dataset. The desired total sample of 281 was then allocated proportionally across these strata to preserve the relative composition of the underlying population. From each stratum, we randomly selected the required number of schools. This ensured that location, technology access, and school size were well balanced between the schools assigned to the control group and those left in the intervention.

Intervention:
Every child in the participating Jardin, Pre-school classrooms in each school will be assessed using the LanguageScreen app (https://oxedandassessment.com/language_screen). This test assesses four core language skills: expressive vocabulary, receptive vocabulary, sentence repetition, and listening comprehension. This testing will be conducted by school staff. Scoring of responses is done online using the app.

After pre-test, all children in each intervention school will receive the programme for 20 weeks from June to October 2025. Children in the waiting list control group will receive the intervention a few months after post-test. Children participating in the intervention will benefit from additional small-group and individual teaching sessions. This includes children identified through the whole-class screening as having language weaknesses. Once the intervention group has completed the 20-week programme, all children in every participating class will be assessed again using the same assessments.

Intervention Type
Behavioural

Primary outcome(s)
A latent language variable created from the four LanguageScreen subtests (Receptive Vocabulary, Expressive Vocabulary, Listening Comprehension and Sentence Repetition) measured at pretest (baseline) in May 2025 and at posttest (on completion of the 20-week intervention in October to November 2025)

Key secondary outcome(s)
There are no secondary outcome measures

Completion date

30/11/2025

Eligibility

Key inclusion criteria
1. Children must be in Jardin or Pre-school class
2. Children must be aged 4 to 7 years at pretest

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
7 Years

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
19/05/2025

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
Paraguay

Study participating centre
1281 schools across Paraguay
Paraguay
-

Sponsor information

Organisation
OxEd & Assessment

Funder(s)

Funder type
Government

Funder Name
Minister of Education and Science, Paraguay

Results and Publications

Individual participant data (IPD) sharing plan
All performance data from the participants will be automatically recorded by the LanguageScreen app and uploaded to OxEd servers at https://py.programaneli.com.

This data will be stored on password-protected, double-encrypted servers. Back-ups will take place weekly during data collection to minimise risks around data loss. After the study concludes, the data will be archived on OxEd's servers according to OxEd's policy for the required retention period (10 years), after which it will be securely destroyed.

Limited personal data will be transferred to and processed in Paraguay by the Ministry of Education and Science. Adequate safeguards, consistent with the UKGDPR and the Data Protection Act2018, are in place as follows:
1. Data minimisation &pseudonymisation – Before any export, direct identifiers (names, dates of birth, addresses) are removed and replaced with unique study codes; the re-identification key is stored only on OxEd & Assessment encrypted server in the UK.
2. Secure transfer – Pseudonymised files are transmitted from the OxEd's secure server via SFTP over an encrypted VPN connection. No data are sent by e mail or consumer cloud services.
There are other contractual protections signed by both parties (MEC and OxEd) formalised in a data sharing and processing agreement. These arrangements provide a level of protection essentially equivalent to that required within the EEA, thereby meeting the adequacy standard in Article46GDPR

IPD sharing plan summary
Stored in non-publicly available repository, Data sharing statement to be made available at a later date