

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

Submission date 18/05/2025	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/05/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/05/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 Jardín 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 Jardín 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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, OxEEd & 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

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Treatment

Participant information sheet

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 measure

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)

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/03/2025

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

Age group

Child

Lower age limit

4 Years

Upper age limit

7 Years

Sex

Both

Target number of participants

100000

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

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Sponsor information

Organisation

OxEd & Assessment

Sponsor details

3 Cartwright Way

Bardon Hill

Coalville

England

United Kingdom

LE67 1UB

-

info@oxedandassessment.com

Sponsor type

Research organisation

Website

<https://oxedandassessment.com/>

Funder(s)

Funder type

Government

Funder Name

Minister of Education and Science, Paraguay

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. No additional documents are available.

Intention to publish date

31/01/2026

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 Act 2018, 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 Article 46 GDPR

IPD sharing plan summary

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