

# Evaluation of a language intervention in Nursery classrooms

<b>Submission date</b> 25/03/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study will evaluate the efficacy of the Nuffield Early Language Intervention – Nursery (NELI-N) programme, which is a 20-week language enrichment programme for children in nursery in the year before they start formal education (aged 3 - 4 years). The programme revolves around shared, interactive storybook reading and guided play. It has a whole class component, designed to enrich the language of all children in nursery, while also providing additional support with small group and individual sessions to improve the spoken language of children in nursery with language weaknesses. It is delivered by trained Nursery teachers and assistants.

The current trial will seek evidence for the efficacy of the programme in improving language skills and remediating language weaknesses of children in Nursery classrooms.

### Who can participate?

Children attending nursery in the autumn term of 2019 (aged 3 – 4) in 60 primary schools in the UK.

### What does the study involve?

Before the language enrichment programme begins all children in all participating nursery classrooms undergo a short app-based language assessment of four core language skills: expressive vocabulary, receptive vocabulary, sentence repetition and listening comprehension. Behavioural adjustment to nursery and knowledge of a selection of the vocabulary that will be taught during the intervention programme is also assessed.

From the language assessment, the 6 children in each participating nursery with the poorest language scores are selected for detailed language assessment.

After pretesting is completed, schools are randomly allocated to one of two groups to either receive the Nuffield Early Language Intervention – Nursery (NELI-N) programme or not receive it. Intervention group schools then receive the programme for 20 weeks (January to June 2020). Once the programme has been completed, all children in every nursery are assessed twice again, using the same assessments at posttest (the end of the intervention in June / July 2020) and at delayed posttest (roughly 6 months after the Intervention is completed in January/February 2021). The language skills of children in intervention schools will be compared to those in control schools to see how much the children who took part have improved as a result of the NELI-N programme.

What are the possible benefits and risks of participating?

Children in the intervention schools will benefit from additional teaching designed to improve their oral language skills. Schools in the control group are offered the Nuffield Early Language Intervention – Nursery (NELI-N) programme once the study is completed. There are no anticipated risks of participation.

Where is the study run from?

The University of Oxford (United Kingdom)

Who is funding the study?

The Nuffield Foundation

Who is the main contact?

Dr Gillian West

[gillian.west@education.ox.ac.uk](mailto:gillian.west@education.ox.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Gillian West

### ORCID ID

<https://orcid.org/0000-0002-4413-3601>

### Contact details

The Department of Education,

15 Norham Gardens

Oxford

United Kingdom

OX2 6PY

01865 274021

[gillian.west@education.ox.ac.uk](mailto:gillian.west@education.ox.ac.uk)

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

N/A

## Study information

## **Scientific Title**

The efficacy of an intensive 20-week language enrichment intervention in nursery classrooms: a cluster-randomised controlled trial

## **Acronym**

NELI-N

## **Study objectives**

The current trial will seek evidence for the efficacy of The Nuffield Early Language Intervention programme in improving language skills and remediating language weaknesses in this age group. Receptive and expressive vocabulary, grammar and narrative skills will be assessed.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 14/03/2019, Departmental Research Ethics Committee (DREC) in the Department of Education, The University of Oxford (15 Norham Gardens, Oxford, OX2 6PY; research.office@education.ox.ac.uk), ref: ED-CIA-19-145

## **Study design**

Cluster randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Other

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

Language learning difficulties

## **Interventions**

Phase 1 – Screening. Every child in participating nursery classrooms will be assessed using the Automated Test of Language Abilities (ATLAS). This test assesses four core language skills: expressive vocabulary, receptive vocabulary, sentence repetition and listening comprehension. This testing will be conducted by nursery staff. Scoring of responses is done online using the app. These 4 subtests define a single language factor well and the scores for all 4 tests combined have excellent reliability ( $\alpha = .93$ ).

Children's behavioural adjustment will also be assessed, using the behavioural adjustment subscale of The Brief Early Skills and Support Index (BESSI: Hughes, Daly, Foley, White, & Devine, 2015), a teacher rating scale of children's behaviour.

Children will also be tested on their knowledge of a selection of the vocabulary that will be taught during the intervention programme, using tests of expressive picture naming and receptive picture selection.

Phase 2 – In-depth testing.

The 6 children in each participating nursery classroom with the poorest language scores (based on a composite z-score from the 4 ATLAS subtests) will be selected for further testing in Phase 2 as follows: CELF recalling sentences subtest, CELF expressive vocabulary subtest, Renfrew Action Picture test (information and grammar). An additional 4 children (without language difficulties) will be selected randomly from each classroom to receive these additional language

tests.

After screening is completed, schools will be randomised within each geographical area to one of two arms: intervention vs control. Randomisation will be conducted by an independent body. Intervention schools will receive the NELI-N programme and training in its use by the research team. The control schools will continue with normal teaching practices and will not administer the programme. Control schools will be offered the NELI-N programme the following year.

ATLAS testing and behavioural assessment at posttest will be conducted by school staff and individually administered language assessments will be given by external testers trained to administer the tests by the research team.

Schools will be randomised (within each geographical area) by an independent body, such as the University of Oxford Clinical Trials Unit, into one of two arms: intervention vs control.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

The primary outcome will be a language latent variable defined by loadings from 4 ATLAS subtests (expressive vocabulary, receptive vocabulary, sentence repetition, and listening comprehension) plus the individually administered language tests (CELF recalling sentences subtest, CELF expressive vocabulary subtest, Renfrew Action Picture test (information and grammar). This language latent variable will be created for baseline, posttest (20 weeks) and delayed posttest (circa 40 weeks). Analyses will be based on latent variable ANCOVA models implemented in an SEM framework. The pretest latent language variable will be the covariate, and the posttest or delayed posttest latent variables will be the outcome measures. Errors for the language latent variable indicators may be correlated to provide an adequate model fit. The effects of the intervention will be measured by the  $\gamma$ -standardized 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 (60 Schools).

Separate ANCOVA models will be conducted to assess the effects of the language intervention programme on 1. Typically developing children (those not identified as having poor language skills); and 2. Children identified as having language difficulties (the 6 children in each class with the lowest language composite score who will get extra small group and individual language teaching).

## **Key secondary outcome(s)**

The secondary outcome measures taken at baseline, posttest and delayed posttest will be:

1. Teachers' ratings of children's behaviour at school, using the behavioural adjustment subscale of The Brief Early Skills and Support Index (BESSI)
2. Knowledge of taught vocabulary assessed using expressive picture naming and receptive picture selection tests. These secondary analyses will use hierarchical linear models with random intercepts for schools.
3. Children's letter sound knowledge and early word reading skill, assessed with subtests from the York Assessment of Reading for Comprehension (YARC) at delayed posttest only (circa 40 weeks after baseline). We will assess the extent to which children in the intervention groups (separately for typically developing children and children with language difficulties) show improvements, using latent variable ANCOVA models with the language pretest latent variable

as the pretest and a latent variable for letter-sound knowledge or Early Word Reading as the outcome latent variables (Latent variables for these two outcome measures will be constructed by using item parcelling)

**Completion date**

30/12/2020

## Eligibility

**Key inclusion criteria**

1. Attending nursery within a state primary school during the autumn school term in 2019.
2. Aged 3 to 4 years at pretest
3. Children receiving in-depth language assessments and additional targeted intervention support will be selected for having language weaknesses in comparison to their peers at pretest.

**Participant type(s)**

Other

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

3 years

**Upper age limit**

4 years

**Sex**

All

**Total final enrolment**

438

**Key exclusion criteria**

1. Start nursery for the first time after 1st December 2019
2. Significant visual impairment
3. Significant auditory impairment
4. Significant behavioural difficulties, such that they would not be able to take part in whole class or small group activities.

**Date of first enrolment**

01/04/2019

**Date of final enrolment**

30/07/2019

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**The University of Oxford**

The Department of Education

15 Norham Gardens

Oxford

United Kingdom

OX2 6PY

**Sponsor information****Organisation**

University of Oxford

**ROR**

<https://ror.org/052gg0110>

**Funder(s)****Funder type**

Charity

**Funder Name**

Nuffield Foundation

**Alternative Name(s)**

NuffieldFound

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The dataset used for analysis during the current study will be stored in a non-publicly available repository (<https://reshare.ukdataservice.ac.uk>) after completion of the trial. The dataset will contain only anonymised data and will include scores for the assessments taken at pretest, posttest and delayed posttest.

## IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		23/01/2024	24/01/2024	Yes	No