

Evaluation of a language intervention in Nursery classrooms

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

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

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Contact information

Type(s)

Scientific

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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 y-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

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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-publically 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?
Results article		23/01/2024	24/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes