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Evaluation of a language intervention in Nursery classrooms

Submission date
25/03/2019

Recruitment status
No longer recruiting

Registration date
26/03/2019

Overall study status
Completed

Last Edited
24/01/2024

Condition category
Mental and Behavioural Disorders

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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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).

Secondary outcome measures

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)

Overall study start date
01/01/2019

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

Age group
Child

Lower age limit
3 Years

Upper age limit
4 Years

Sex
Both

Target number of participants
The exact numbers of children participating in the trial is not known until recruitment is completed. We will seek to recruit at 60 schools with nursery classes. All children aged 3 to 4 who are already attending or will begin attending participating nurseries during the autumn term 2019 will be eligible for participation. Children starting nursery with staggered dates later in the school year will not be enrolled into the trial. Within this sample, the 6 children in each

setting with the poorest language skills will be identified for in-depth testing and additional targeted intervention, giving a sample of 360 children with language weaknesses (180 intervention and 180 control).

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
England

United Kingdom

Study participating centre
The University of Oxford
The Department of Education
15 Norham Gardens
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Website
http://www.education.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Nuffield Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of the study will be published in a peer-reviewed scientific journal at the end of the trial.

Intention to publish date
01/03/2021

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

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/01/2024	24/01/2024	Yes	No