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Language intervention in the early years - comparing the effectiveness of language intervention approaches for pre-school children with language difficulties

Submission date
19/12/2019

Recruitment status
No longer recruiting

Registration date
08/01/2020

Overall study status
Completed

Last Edited
11/02/2025

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 compare the efficacy of three intervention approaches which aim to improve children's oral language abilities. If children are to enter school ready for the challenges and opportunities of education, then robust language skills are essential. Children reaching 4 years-of-age with poor language are likely to have persisting difficulties warranting a diagnosis of Developmental Language Disorder (DLD) with associated risks of poorer educational, employment and psychosocial outcomes extending into adulthood. Between 7 – 19% of pre-school children have poor language development, rising to up to 50% in the most socially disadvantaged groups, making early preventative interventions a priority. However, the development of effective preschool language interventions which can be delivered at scale has proved challenging. Few interventions have been rigorously evaluated using Randomised Controlled Trials (RCTs) and where they have many have proved ineffective. Furthermore for RCTs with positive findings, application to practice can be problematic. Reasons include high levels of resource to effect change, small or circumscribed effects, or limited acceptability and accessibility to children and families from a range of socio-cultural backgrounds. This study compares the efficacy of three intervention approaches: Building Early Sentences Therapy (BEST), Derbyshire Language Scheme (DLS), and Continuing Classroom Support (CCS). BEST is an intervention for pre-school children with severe language difficulties which aims to improve children's use and understanding of sentences. BEST is based on 'usage-based' linguistic theory. The underlying principle is that by manipulating the nature and quantity of the language a child hears, BEST can promote abstract and flexible knowledge and use of a range of sentence structures, and so accelerate future language learning. This study will compare BEST with DLS, a widely-used intervention with no explicit theoretical basis but with proven efficacy and high face validity; and with the usual day-to-day language input in nursery (CCS). The aim is to determine whether the interventions differ in their efficacy, whether aspects of children's language profiles predict their progress in the different interventions, whether the interventions differ in the degree to which benefits generalise to broader language and communication skills, and to identify factors which will support the implementation of the study findings to practice.

Update February 2021
Due to COVID-19, the project was suspended in March 2020. The project will resume once schools fully reopen, hopefully in March 2021. Due to the reduction in the timescale available to the study some changes have been made to the project protocol. All changes have been added to this page.
The Continuing Classroom Support (control) arm has been removed from the study. As children have missed out on many months of education it seems unethical to ask children and settings to spend time and effort on assessments without receiving an intervention, especially as recent findings from a research study into Building Early Sentences Therapy indicate that it is more effective than treatment as usual.

Who can participate?
3 – 4-year-old English-speaking children with severe language difficulties

What does the study involve?
Children are recruited from 24 schools in the North East of England. Schools are randomly allocated to the three interventions. Interventions are delivered by trained Research Associates (SLTs or Teachers) in partnership with schools over three waves. Interventions are delivered in groups twice a week for 8 weeks. The children's language and functional communication are assessed before and after the intervention and at 4 months follow-up by Research Associates who do not know which treatment the children are receiving.

Due to the delay caused by COVID-19 some schools have left the project. There will now be two waves of interventions. 21 schools have been allocated to wave 1 or wave 2 or both. Follow up assessments will now be conducted 2-3 months after the end of the intervention.

What are the possible benefits and risks of participating?
For the participating schools and children the researchers cannot guarantee that the interventions offered will offer additional benefit. However, they aim to offer the schools the opportunity for a series of CPD sessions delivered by the research team regarding methods to promote language and literacy abilities in the early years. The study is low risk. One aspect which needs to be considered is potentially increased anxiety in families due to their children being identified as needing additional support for their language. This will be mitigated through close partnership working with schools to communicate appropriately with the family and to provide the opportunity to discuss the implications with the research team who are trained Speech and Language Therapists and an ex Early Years Teacher. All children will be able to access SLT services in addition to the research interventions if they so wish.

Where is the study run from?
Primary schools across the North East of England (UK)

When is the study starting and how long is it expected to run for?
July 2019 to June 2022

Who is funding the study?
Heather van der Lely Foundation (UK)

Who is the main contact?
Prof. Cristina McKean
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
LIVELY-2019

Study information

Scientific Title

Language Intervention in the Early Years: comparing the efficacy of Building Early Sentences Therapy and the Derbyshire Language Scheme in improving language and functional communication outcomes in pre-school children with language disorder

Acronym
LIVELY

Study objectives
Building Early Sentences Therapy (BEST) (http://www.buildingearlysentencestherapy.co.uk) is a new intervention for pre-school children with severe language difficulties which aims to improve children's use and understanding of sentences. BEST is based on 'usage-based' linguistic theory. The underlying principle is that by manipulating the nature and quantity of the language a child hears, BEST can promote abstract and flexible knowledge and use of a range of sentence structures, and so accelerate future language learning.

The Derbyshire Language Scheme (DLS) is one of the most widely-used interventions for pre-school children with language disorder in the UK. There is some evidence of its effectiveness in improving language comprehension outcomes.

For monolingual English speaking children, the researchers will compare BEST with DLS, and with the usual day-to-day language input in nursery (Continued Classroom Support (CCS). DLS and BEST interventions will be matched in treatment intensity, context, duration and agents of delivery.

Research questions:
1. Are BEST and DLS effective in improving language and functional communication outcomes?
2. Is BEST more effective than DLS, suggesting that it is the specific learning mechanisms exploited by BEST which promote change?
3. Does BEST accelerate future language learning after the intervention is complete?
4. Are there differential effects across language interventions depending upon the children's language profiles in terms of severity, receptive-expressive language profile and/or scores on morpho-phonological processing.
5. Do interventions differ in the degree to which benefits transfer to outcomes of varying 'distance' from the intervention targets (near, intermediate, far)?
6. To what degree do intention to treat and per-protocol analyses differ and what could this tell us about implementation of effective interventions in practice?

Added 24/02/2021:
As a result of changes made due to COVID-19 the Continued Classroom Support arm has been removed from the project. Participating schools will still be asked about their usual provision for children with language difficulties.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2019, University of Newcastle Ethics Committee (Faculty of Humanities and Social Sciences, Great North House, Sandyford Road, Newcastle upon Tyne, NE1 8ND, UK; Tel: +44 (0)191 208 6349; Email: Wendy.Davison@ncl.ac.uk), ref: 15153

Primary study design
Interventional

Study design
Cluster randomized control trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Language disorder

Interventions
Current interventions as of 24/02/2021:

The Heather van der Lely Foundation has granted funding to Newcastle and Manchester Universities to conduct a cluster randomised control trial across 24 schools in the North East of England. Schools will be recruited from Newcastle, South Tyneside and Gateshead. If more than the target number are recruited, 24 will be randomly chosen to be part of the trial. This group of 24 will be split into two geographical areas of 12 schools (areas A and B) to facilitate timely delivery of the interventions by the research team and to complete intervention delivery and data collection within allocated resources.

As a result of changes made due to COVID-19 the number of schools involved in the project for each wave of the study has been reduced. Some schools have left the project meaning there are now 21 schools participating. Some of these 21 schools will work with the project during the first wave (March-Sept 2021), up to 16 schools will work with the project for the second wave (Sept 2021-April 2022). Some will work with the project for both waves. This was determined based on which schools were able to commit to the project. If a school participates in both waves they will remain in the same arm. The schools have been split into two geographical areas.

Schools were randomized to one of three arms; (Building Early Sentences Therapy (BEST), Derbyshire Language Scheme (DLS) and Continued Classroom Support (CCS)). The randomization was undertaken by the minimization method, attempting to balance across the arms on geographic region (A/B) and the proportion of pupils eligible for Pupil Premium (High/Low). The minimization method attempts to balance these factors across the treatment arms. A median split on the school proportion of pupils eligible for Pupil Premium was used as a proxy for level of social disadvantage.

As a result of delays caused by COVID-19 schools will be randomised to one of two arms.

The process of randomisation has two stages; the first stage assigns randomly a number to each school in the consenting group of x schools, between 1 and x (ie as if the schools were consenting one at a time). The schools are then entered in that order to the second stage, randomisation to two groups (BEST and DLS) based on the pseudo random minimisation method. The minimisation here attempts to balance the groups on two factors, region and Pupil Premium (two levels – high and low based on a median split). The first school to enter the randomisation does so based on random number draw (above or below 0.5) to one of the groups. Subsequent schools are assigned to the group which will minimise the difference in the groups with a probability of 0.75. Any ties are resolved by random number draw, similar to first entry.

Schools will be allocated using the minimisation pseudo random method to one of the two arms:
1. Building Early Sentences Therapy (BEST)
2. Derbyshire Language Scheme (DLS)

BEST
BEST is based on 'usage-based' linguistic theory. Rather than innate, grammar is construed as 'constructed', using domain general processing mechanisms generalising across the input. The resulting theoretical model has the potential to bring together linguistic and cognitive /processing accounts of Language Disorders. BEST is the first pre-school language intervention based on usage-based linguistic theory: the underlying principle of the intervention is that the nature, distribution and quantity of the language a child hears is central to acquisition. Through manipulation of these factors, children are supported to harness the cognitive mechanisms posited to underpin the process of early language acquisition: intention reading, culturallear ning, schematization and analogy. BEST aims to improve children's use and understanding of two, three and four clause element sentences (i.e. 2: The girl is jumping; 3: the boy is eating a banana; 4: the baby is putting the cup on the table). Over 16, twice weekly sessions children learn to use 16 different verbs in simple sentences of varying structure (SV, SVO, SVOO, SVOA), and develop abstract representations of the grammar of these sentences, an accomplishment thought to then accelerate future language learning. The BEST intervention exposes children to models of the target sentences in a controlled way, involving both massed and distributed exposure, with controlled variation within the target sentences and controlled contrast between the sentences heard, all presented within a joint action routine.
1. Massed exposure ensures children hear high numbers of models of the same or similar sentences in a single therapy session, providing the large number of repetitions shown to be necessary for children with Developmental Language Disorder (DLD) to learn new language structures.
2. Distributed exposure ensures children hear the target items spread across a number of days (in this case over 16 therapy sessions); conditions shown to be associated with greater retention of novel learning in language and other domains.
3. Variation of the lexical items within the sentences is used to support children to identify patterns in the sentences (schematisation) and to identify groups of words which can be used in particular positions in sentences (categorisation).
4. Contrast is used to promote analogy through alignment of sentences with similar structures but different verbs in the same joint action routine. The process of analogy allows children to develop abstract representations of the semantic roles that make up sentence structures (e.g. agent action patient – the boy is eating the lolly). The development of abstract representations of these roles supports children to use them in sentences flexibly and creatively, allowing the child to learn other related structures more readily, and increasing the child's rate of language development.
5. Joint action routines are used to create a predictable play sequence wherein the child understands the purpose and structure of the communicative interaction. This then supports the child to infer (intention read) the communicative intention of the adult and so the meaning of the sentences they hear. The combination of this intention reading with imitation (cultural learning) allows the child to learn the meaning and structure of the sentences they hear in the routine.

DLS
The DLS is one of the most widely used language interventions in the UK. It is comprised of a set of language assessments and manuals which contain descriptions of individual and group activities aimed at improving a child's use and understanding of language. They start at a low level where it is presumed that the child has no comprehension of language and no expressive

language ability. From this point the syllabus moves in small steps to a level where the child is expected to follow a sequence of two commands after hearing them once only (eg: Put your colouring book on the table, and fetch me your plimsolls). The scheme is made up of teaching activities linked to language objectives which increase in the number of information carrying words the child needs to understand.

For the purposes of the LIVELY study an Adapted DLS program has been developed with the DLS author to standardise the resources, activities and progression through the program choosing a subset of the teaching activities in the full DLS program. Children will be grouped according to their receptive language abilities and sessions will involve receptive and expressive language components encouraging children to progress to the next step in the DLS program through structured play activities.

Continued Classroom support
In this treatment arm Schools will continue to offer the support they would usually offer to children they have identified as having significant language needs. This is in recognition of the fact that many schools offer additional interventions and strategies to promote language development and to test whether BEST and DLS offer any advantage over and above usual practice. Class teachers will be interviewed to describe the approaches in place in their settings.

As a result of changes made due to COVID-19 the Continued Classroom Support arm has been removed from the project.

Participants
Consenting children aged 3;05–4;05, identified by teachers as monolingual speakers of English, and not meeting age-related expectations in their language development, will be assessed and included if they:
1. Score ≤ 16th centile on the New Reynell Developmental Language Scales (NRDLS: Edwards et al 2011) expressive and/or receptive subscales
2. Have no reported sensorineural hearing impairment, severe visual impairment or diagnosed learning disability.

From piloting the researchers anticipate approximately 288 children will be eligible and likely to consent using this approach if all schools participate across all 3 waves. This pilot study also suggested that some attrition is likely.

As intra-cluster correlations are not known a simple power calculation using Cohen's d power tables (Cohen 1988) has been completed. At 80% power, two-tailed α of .05 and an estimated effect size of .5 (derived from Hagen et al 2017 -the most similar recent trial) the minimum sample required is 64 children in each arm (i.e. 192 children). Our approach therefore allows for attrition of schools and children.

As a result of changes made due to COVID-19 the number of waves has been reduced from three to two and the number of schools in each wave has also been reduced. The project will now work with approximately 104 children.

Measures will be completed at baseline, outcome (≤ 4 weeks post-intervention) and follow-up (4–6 months post-intervention) and will vary in their hypothesised distance from the intervention taught material.
1. Near: targeted sentence structures assessed through experimenter designed BEST and DLS assessments including picture description eliciting targeted sentence structures and a 'toy test' to assess comprehension of the same structures.

2. Intermediate: NRDLS.
3. Far: FOCUS (Focus on the Outcomes of Communication Under Six); parent and teacher report measure of communicative participation.

At baseline only a measure of morpho-phonological abilities will also be completed (GAPS – Grammar and Phonology Screen). GAPS will also contribute to the moderator analyses described later.

An additional assessment, Vineland 3, will now be been used to provide an estimate of the children's nonverbal and broader developmental profiles.

As a result of changes made due to COVID-19 the follow up assessment will now take place 2 - 3 months after the intervention concludes.

Masking: Baseline, outcome and follow-up will be completed blind to treatment arm: RA 1 will deliver interventions in geographical cluster A and conduct assessments in cluster B; RA 2 will deliver interventions in geographical cluster B and conduct assessments in cluster A.

Treatment Delivery and Fidelity: BEST is manualised and has a standard set of resources. To ensure fair comparison a DLS manual and set of resources will be developed. Approaches used to support children in the CCS schools will be recorded. Interventions will be delivered by RAs trained to deliver the interventions to high levels of fidelity in partnership with school staff. A treatment fidelity observational checklist already exists for BEST. A parallel tool will be developed for DLS and fidelity checks completed from video recordings.

Children in the BEST or DLS arms will receive the intervention delivered by RAs, who are qualified Speech and Language Therapists, twice a week for 8 weeks. Intervention sessions will last approximately 20 minutes and delivered in groups of approximately 4 children depending on the language profiles of the children and timetabling.

Previous interventions:

The Heather van der Lely Foundation has granted funding to Newcastle and Manchester Universities to conduct a cluster randomised control trial across 24 schools in the North East of England. Schools will be recruited from Newcastle, South Tyneside and Gateshead. If more than the target number are recruited, 24 will be randomly chosen to be part of the trial. This group of 24 will be split into two geographical areas of 12 schools (areas A and B) to facilitate timely delivery of the interventions by the research team and to complete intervention delivery and data collection within allocated resources. Schools were randomized to one of three arms; (Building Early Sentences Therapy (BEST), Derbyshire Language Scheme (DLS) and Continued Classroom Support (CCS)). The randomization was undertaken by the minimization method, stratifying by geographic region (A/B) and the proportion of pupils eligible for Pupil Premium (High/Low). The minimization method attempts to balance these factors across the treatment arms. A median split on the school proportion of pupils eligible for Pupil Premium was used as a proxy for level of social disadvantage.

Schools will be allocated using blocked and stratified randomisation within each geographical cluster to one of the three arms:

1. Building Early Sentences Therapy (BEST)
2. Derbyshire Language Scheme (DLS)
3. Continued Classroom Support (CCS)

BEST

BEST is based on 'usage-based' linguistic theory. Rather than innate, grammar is construed as 'constructed', using domain general processing mechanisms generalising across the input. The resulting theoretical model has the potential to bring together linguistic and cognitive /processing accounts of Language Disorders. BEST is the first pre-school language intervention based on usage-based linguistic theory: the underlying principle of the intervention is that the nature, distribution and quantity of the language a child hears is central to acquisition. Through manipulation of these factors, children are supported to harness the cognitive mechanisms posited to underpin the process of early language acquisition: intention reading, cultural learning, schematization and analogy. BEST aims to improve children's use and understanding of two, three and four clause element sentences (i.e. 2: The girl is jumping; 3: the boy is eating a banana; 4: the baby is putting the cup on the table). Over 16, twice weekly sessions children learn to use 16 different verbs in simple sentences of varying structure (SV, SVO, SVOO, SVOA), and develop abstract representations of the grammar of these sentences, an accomplishment thought to then accelerate future language learning. The BEST intervention exposes children to models of the target sentences in a controlled way, involving both massed and distributed exposure, with controlled variation within the target sentences and controlled contrast between the sentences heard, all presented within a joint action routine.

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2. Distributed exposure ensures children hear the target items spread across a number of days (in this case over 16 therapy sessions); conditions shown to be associated with greater retention of novel learning in language and other domains.
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4. Contrast is used to promote analogy through alignment of sentences with similar structures but different verbs in the same joint action routine. The process of analogy allows children to develop abstract representations of the semantic roles that make up sentence structures (e.g. agent action patient – the boy is eating the lolly). The development of abstract representations of these roles supports children to use them in sentences flexibly and creatively, allowing the child to learn other related structures more readily, and increasing the child's rate of language development.
5. Joint action routines are used to create a predictable play sequence wherein the child understands the purpose and structure of the communicative interaction. This then supports the child to infer (intention read) the communicative intention of the adult and so the meaning of the sentences they hear. The combination of this intention reading with imitation (cultural learning) allows the child to learn the meaning and structure of the sentences they hear in the routine.

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expected to follow a sequence of two commands after hearing them once only (eg: Put your colouring book on the table, and fetch me your plimsolls). The scheme is made up of teaching activities linked to language objectives which increase in the number of information carrying words the child needs to understand.

For the purposes of the LIVELY study an Adapted DLS program has been developed with the DLS author to standardise the resources, activities and progression through the program choosing a subset of the teaching activities in the full DLS program. Children will be grouped according to their receptive language abilities and sessions will involve receptive and expressive language components encouraging children to progress to the next step in the DLS program through structured play activities.

Continued Classroom support
In this treatment arm Schools will continue to offer the support they would usually offer to children they have identified as having significant language needs. This is in recognition of the fact that many schools offer additional interventions and strategies to promote language development and to test whether BEST and DLS offer any advantage over and above usual practice. Class teachers will be interviewed to describe the approaches in place in their settings.

Participants
Consenting children aged 3;05–4;05, identified by teachers as monolingual speakers of English, and not meeting age-related expectations in their language development, will be assessed and included if they:
1. Score ≤ 16th centile on the New Reynell Developmental Language Scales (NRDLS: Edwards et al 2011) expressive and/or receptive subscales
2. Have no reported sensorineural hearing impairment, severe visual impairment or diagnosed learning disability.

From piloting the researchers anticipate approximately 288 children will be eligible and likely to consent using this approach if all schools participate across all 3 waves. This pilot study also suggested that some attrition is likely.
As intra-cluster correlations are not known a simple power calculation using Cohen's d power tables (Cohen 1988) has been completed. At 80% power, two-tailed α of .05 and an estimated effect size of .5 (derived from Hagen et al 2017 -the most similar recent trial) the minimum sample required is 64 children in each arm (i.e. 192 children). Our approach therefore allows for attrition of schools and children.

Measures will be completed at baseline, outcome (≤ 4 weeks post-intervention) and follow-up (4–6 months post-intervention) and will vary in their hypothesised distance from the intervention taught material.
1. Near: targeted sentence structures assessed through experimenter designed BEST and DLS assessments including picture description eliciting targeted sentence structures and a 'toy test' to assess comprehension of the same structures.
2. Intermediate: NRDLS.
3. Far: FOCUS (Focus on the Outcomes of Communication Under Six); parent and teacher report measure of communicative participation.
At baseline only a measure of morpho-phonological abilities will also be completed (GAPS – Grammar and Phonology Screen). GAPS will also contribute to the moderator analyses described later.

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Treatment Delivery and Fidelity: BEST is manualised and has a standard set of resources. To ensure fair comparison a DLS manual and set of resources will be developed. Approaches used to support children in the CCS schools will be recorded. Interventions will be delivered by RAs trained to deliver the interventions to high levels of fidelity in partnership with school staff. A treatment fidelity observational checklist already exists for BEST. A parallel tool will be developed for DLS and fidelity checks completed from video recordings.

Children in the BEST or DLS arms will receive the intervention delivered by RAs, who are qualified Speech and Language Therapists, twice a week for 8 weeks. Intervention sessions will last approximately 20 minutes and delivered in groups of approximately 4 children depending on the language profiles of the children and timetabling.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 24/02/2021:

The outcomes of interest are children's oral language development and their communicative participation. Children are assessed on all outcome measures at three time-points: baseline, outcome and follow-up. Baseline testing will happen when children are identified at the start of each wave, Outcome testing within 4 weeks of end of intervention, and Follow up testing approximately 8-12 weeks after intervention. Intervention group comparisons will be made on measures at outcome and at follow-up.

Intention to treat and per protocol analyses will be conducted on all outcome measures which vary in their hypothesised distance from the intervention taught material.

1. Near: targeted sentence structures assessed through experimenter designed BEST and DLS assessments including picture description eliciting targeted sentence structures and a 'toy test' to assess comprehension of these sentences.
2. Intermediate: New Reynell Developmental Language Scales.
3. Far: FOCUS (Focus on the Outcomes of Communication Under Six); parent and teacher report measure of communicative participation.

Use of near, intermediate and far outcomes allow exploration of differences between interventions with respect to the degree to which learning transfers to broader language skills and communicative participation. Hence we do not make a distinction between primary and secondary outcomes but rather explore the effects on all 3 outcomes. It is possible that different approaches may have differing effects for each outcome.

For intention-to-treat analyses the average outcome score across the three treatment arms on the relevant outcome measure will be used for all missing data. Per-protocol analyses will be conducted on all children with complete outcome data. Qualitative data regarding barriers and enablers to intervention delivery (reflective field notes) will be triangulated with a comparison between intention-to-treat and per-protocol outcomes to inform successful implementation of effective interventions into practice.

Moderator analyses will be completed to identify whether differential effects across language interventions exist depending upon the children's language profiles (severity, receptive-expressive language difficulties and/or scores on morpho-phonological processing).

A moderator analysis will be completed using Vineland 3 scores to determine whether differential effects exist depending on non-verbal ability.

Finally, a latent variable outcome analysis will be conducted using the three direct assessments of oral language using multilevel structural equation modelling (SEM) to account for the cluster randomisation. The outcome will be a latent language variable created from the New Reynell Developmental Language Scales, the BEST and DLS language assessments. The rationale for this approach is to evaluate to what degree the interventions may affect a unitary underlying language factor. The effects of the intervention will be measured by an appropriate effect size such as standardized differences in means comparing the two treatment arms.

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Previous primary outcome measure:

The outcomes of interest are children's oral language development and their communicative participation. Children are assessed on all outcome measures at three time-points: baseline, outcome and follow-up. Baseline testing will happen when children are identified at the start of each wave, Outcome testing within 4 weeks of end of intervention, and Follow up testing approximately 8-12 weeks after intervention. Intervention group comparisons will be made on measures at outcome and at follow-up.

Intention to treat and per protocol analyses will be conducted on all outcome measures which vary in their hypothesised distance from the intervention taught material.

1. Near: targeted sentence structures assessed through experimenter designed BEST and DLS assessments including picture description eliciting targeted sentence structures and a 'toy test' to assess comprehension of these sentences.
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Moderator analyses will be completed to identify whether differential effects across language interventions exist depending upon the children's language profiles (severity, receptive-expressive language difficulties and/or scores on morpho-phonological processing).

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

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Aged 3.5 - 4.5 years
2. Monolingual speaker of English/English as main language
3. Scoring at or below the 16th centile on a standardised play-based language assessment
4. With the ability to participate in a small group learning context

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3.5 Years

Upper age limit
4.5 Years

Sex
All

Total final enrolment
102

Key exclusion criteria
1. Sensorineural hearing impairment
2. Severe visual impairment
3. Diagnosed learning disability

Date of first enrolment

01/02/2020

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
United Kingdom

Study participating centre
Primary schools across the North East of England
United Kingdom
-

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Charity

Funder Name
Heather van der Lely Foundation

Results and Publications

Individual participant data (IPD) sharing plan
At the end of the project, once resulting publications have been accepted, the data collected will be de-identified and made available as “open data” through a research data repository (https://research.ncl.ac.uk/rdm/sharing/). This means the de-identified study data will be publicly available and may be used by other researchers for purposes not related to this study. It will not

be possible to identify the children or schools from the “open data”. Parents/carers, headteachers, teachers and teaching assistants will be asked to sign consent forms prior to data collection starting.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes