Evaluation of Infant Language Link: a twoarmed cluster randomised trial Evaluation Protocol



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PROJECT TITLE	Evaluation of Infant Language Link, a two-armed cluster randomised trial
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TRIAL DESIGN	Two-arm cluster randomised controlled trial with random allocation at school level
TRIAL TYPE	Efficacy
PUPIL AGE RANGE AND KEY STAGE	Age 5-6, KS1
NUMBER OF SCHOOLS	170
NUMBER OF PUPILS	3400
PRIMARY OUTCOME MEASURE AND SOURCE	Language and communication (CELF and RAPT)
SECONDARY OUTCOME MEASURE AND SOURCE	Language and communication (CELF and RAPT)

Protocol version history

VERSION	DATE	REASON FOR REVISION
2.0	7 May 2024	Updating approach to creating primary outcome measure and compliance indicators
1.0 [original]		N/A

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Study rationale and background

For children with speech and language difficulties, early intervention is crucial for success in education (Bercow, 2018; Law, Charlton and Asmussen, 2017). Difficulties can arise with strands of language development including phonology, morphology, syntax, semantics and pragmatics. As language serves instrumental, regulatory, interactional, personal, representational, heuristic and imaginative functions (Halliday, 1978), it is imperative to social, emotional and cognitive development. Early experiences of language are strongly associated with academic performance (Roulstone, 2011), and the early identification of speech and language needs is critical (Oracy All Party Parliamentary Group, 2021). Furthermore, there is emerging evidence that the Covid-19 pandemic has impacted negatively on the language experiences of some of the youngest learners (Crew, 2021; Tracey et al, 2022).

In recent years the evidence around targeted early years language interventions has been growing. The Nuffield Early Language Intervention (NELI) is used widely in schools and has demonstrated efficacy (Sibieta et al, 2016) and effectiveness (Dimova et al, 2020) in large-scale randomised controlled trials. Another programme, Parents and Children Together (PACT), involves a parent-delivered language intervention and showed a positive impact at both immediate and delayed post-test when evaluated by the developers at 22 children's centres (Burgoyne et al, 2018). However, a larger EEF-funded efficacy trial incorporating 450 pupils across 43 sites found no evidence of additional progress among pupils allocated to the intervention group at delayed post-test (Menzies et al, 2022). The trial was unable to collect primary outcome data immediately after the intervention due to the Covid-19 pandemic, and had to use an alternative, teacher-administered language measure as primary outcome. Nonetheless, the findings from the delayed post-test were deemed to have a moderate-to-high security rating, reflecting a degree of confidence in the findings.

Targeted interventions sometimes fail to reach the correct pupils (Lee and Pring, 2016:140). Research from Australia has shown that teachers can erroneously identify pupils as needing support or overlook those for whom further assistance is required (Antoniazzi et al, 2010). The most recent evaluation of the NELI, which also used a standardised screening tool, found that some teachers would have preferred to make their own decisions about which pupils received support. Despite this, the intervention had a positive impact on the pupils selected through standardised screening (Dimova et al, 2020:48-49).

Infant Language Link enables schools to identify and support children in reception, Y1 and Y2 with mild to moderate language needs. The intervention uses a graduated approach to determine the level and intensity of support for pupils (as detailed in the SEND Code of Practice, see DfE and DoH, 2015). This tiered structure is a crucial element of the programme, which incorporates whole class provision and additional support for pupils found to be in need. The mechanism for identifying these pupils is another central feature.

Infant Language Link attempts to address the issues around pupil selection through using a standardised universal screening tool to accurately assess pupil ability (Burton et al, 2021). Selecting the pupils who will benefit most from targeted support is clearly crucial in creating conditions where the intervention can demonstrate impact in an efficacy trial.

Survey data from Language Link, based on a sample of 962 teachers, SENCOs, teaching assistants and senior leaders, found that 93% of these respondents thought the programme made a positive difference to their children, while 71% said they changed the way they worked with children because of the programme (Mustoe-Playfair and Bingham, 2020).

These findings suggest that the programme has been well received when implemented with reception pupils, yet an efficacy trial will provide more robust evidence of its impact for Year 1 pupils.

Intervention

Here, the intervention is described using the TIDIER framework. The logic model diagram agreed with the developer during the set-up stage has been included in the Appendix. A description of the underlying mechanisms and assumptions at each step can be found in the IPE section of this protocol.

Control schools are expected to operate on a business-as-usual basis during the study year. They do not have access to any of the intervention resources, including the initial pupil screening.

Name

Infant Language Link

Why (theory/rationale)

The importance of early intervention for pupils struggling with language development is widely recognised. Infant Language Link is an intervention that enables schools to identify and support children who have mild to moderate language needs, using a standardised screening assessment and tiered levels of support.

Who (recipients)

The intervention is designed for schools to identify and support pupils from reception (age 4-5), and provide continued support for pupils in Y1 and Y2 (aged 5-7). For this evaluation it will be delivered to Y1 pupils, although intervention schools will be free to also provide the programme to pupils in reception and Y2 should they wish. All pupils in the class are provided with support, and those identified as needing further support participate in targeted group sessions led by Teaching Assistants.

What (materials)

The online screening tool for assessing pupil language needs is a central part of the intervention. This screening takes place at the start of the intervention period. The Infant Language Link learning materials will be provided to schools; these include 500 group and classroom resources, 12 planned termly language groups, 24 individual teaching plans and 52 handouts for parents.

Guidance notes and session plans for teachers are supplied along with resources to support the delivery of engaging, interactive teaching and learning activities, for example story planners, talk templates and concept cards. The session plans and ILL learning resources enable TAs to deliver the targeted group sessions in a structured way. Tracking sheets allow teachers and TAs to record individual pupil progress.

What (procedures)

As the intervention is delivered in school, SENCOs, teachers and TAs attend webinar training sessions at the start of the programme led by a Speech and Language Therapist from the delivery team. All training sessions are completed before Infant Language Link is implemented.

The first webinar is an *Introduction to Language Link*. This covers the importance of speech and language skills, how they develop, the impact of difficulties and how to carry out the Language Link assessment. This webinar is 1½ hours and is attended by SENCOs, class teachers and TAs.

Following this initial training, staff attend a second webinar based on their role within school. Class teachers and SENCOs attend the *Using Language Link in the Classroom* webinar. This covers using the Language Link whole class strategies and classroom resources, measuring progress and provides an overview of the Language Link interventions. This webinar is 1½ hours.

Teaching assistants attend the **Delivering Language Link Interventions** webinar. The session focuses on setting up and delivering language group interventions and the supplementary teaching programmes. This webinar is 1½ hours.

This prepares the school staff to provide the intervention to participating pupils.

Following the initial language screening, staff use universal strategies for all children in the class. Four core high quality teaching strategies for communication in the classroom (Break It Down, Explain Clearly, Check as You Go, and Keep it Visual) are recommended. Resources and training for classroom-based staff are included as part of a whole school approach. SaLTs from Speech Link are available to schools as a 'helpdesk' for schools to contact if they require support. Pupils identified as having additional needs receive further support through individual and group interventions, as described below.

Who (provider)

School staff receive webinar training, delivered by a speech and language therapist, to both develop understanding of the importance of identifying and supporting Speech, Language and Communication Needs (SLCN) and to enable them to use the package successfully.

How (format)

Teachers deliver the universal element of the intervention to all pupils in class. Targeted group interventions are also delivered to groups of 4-5 pupils by TAs. The amount and type of intervention depends on the child's performance on the initial screening. The minimum intervention is 16 x 30-minute sessions; and the maximum is 32 x 30-minute sessions per school year. A session plan with target aims, key vocabulary, and guidance for completing structured activities is provided for each session. Teacher guidance notes highlight the language skills and vocabulary covered; with advice on developing these in the classroom to support generalisation. Pupil progress within group interventions is tracked. For children who have not made the expected progress, supplementary teaching is recommended. This intensive individual support is delivered for a short time, focusing on a specific area of language difficulty and monitoring progress through testing before and after.

Where (location)

The intervention is delivered in Y1 classrooms at schools in England.

When and how much (dosage)

The intervention will be delivered during the 2023/24 school year. It is expected that teacher training will take place immediately after the autumn half term, so the individual pupil

screening in intervention schools is likely to begin in November. Delivery will run until the summer half term. Ideally sessions will be delivered twice per week during this time.

Tailoring (adaptation)

Normally the programme begins by screening reception pupils who then participate in the intervention, with continued support through Y1 and Y2 as described above. However, for this trial the focus will be on Y1 due to the lack of existing evidence around interventions working with this year group. The timeframe for delivering the targeted sessions has also been compressed.

Impact evaluation

Research questions

- 1. Primary research question: What is the impact of the intervention on Year 1 pupils' language and communication skills, as measured by the primary outcome (CELF linguistic concepts and sentence comprehension subtests and RAPT combined)?
- 2. Secondary research questions:
 - a. What is the impact of the intervention on the subgroup of Year 1 pupils who received targeted support, as measured by the primary and secondary outcomes?
 - b. What is the impact of the intervention on the subgroup of Year 1 FSM pupils, as measured by the primary outcome?
 - c. What is the impact of the intervention on Year 1 pupils' receptive and expressive language skills as measured by individual subtests of the outcome measure (CELF linguistic concepts and sentence comprehension; RAPT information and grammar).
 - d. What is the impact of the intervention on the subgroup of EAL pupils, as measured by the primary outcome?

Design

This two-arm, two-level clustered efficacy trial is delivered over a single school year to pupils in Y1 classes at intervention schools. Control schools continue with business as usual during the study period. Baseline and outcome testing will be carried out in the first and final half terms of the 2023/24 school year respectively. Further details on pupil testing can be found below.

Table 1: Trial design

Trial design, i	ncluding number of arms	Two-arm, two-level cluster randomised trial
Unit of r	andomisation	School
	ation variables pplicable)	Education Investment Area Existing use of Speech and Language interventions Use of Speech and Language Therapy services
Primary	variable	Language and communication
Primary outcome	measure (instrument, scale, source)	Pearson CELF-5 (sentence comprehension and linguistic concepts subtests) and Renfrew Action Picture Test combined
	variable(s)	Language and communication
Secondary outcome(s)	measure(s) (instrument, scale, source)	Pearson CELF-5 (sentence comprehension 0-26) Pearson CELF-5 (linguistic concepts 0-25) Renfrew Action Picture Test (Information 0-41, grammar 0-39)
Baseline for	Variable	Language and communication
primary outcome	measure (instrument, scale, source)	Pearson CELF-5 (sentence comprehension and linguistic concepts subtests) and Renfrew Action Picture Test combined
Baseline for	variable	N/A
secondary outcome	measure (instrument, scale, source)	Pearson CELF-5 (sentence comprehension 0-26) Pearson CELF-5 (linguistic concepts 0-25) Renfrew Action Picture Test (Information 0-41, grammar 0-39)

Randomisation

Randomisation will be conducted at school level to minimise spillover risk. The procedure will be conducted using the 'stratarand' command in Stata. All schools will be allocated at the same time. Three stratifiers will be used, specifically whether a school: is/not (1/0) in an Education Investment Area, does/not (1/0) use any relevant interventions (such as NELI, Wellcomm and Talk Boost), and uses external speech and language therapy support (to be treated as three categories: none, low frequency, and half-termly or more frequent). This is to reduce the risk of allocation imbalance in areas receiving additional support through undermining the viability of the training, and to mitigate against the use of other relevant interventions or support services confounding the results of this trial. The evaluators will remain blinded to group allocation at the time of randomisation, but it will not be possible to maintain this once the schools have been allocated.

Participants

Any school with at least 20 pupils in the 2023/24 Y1 cohort is eligible for the trial. A maximum of 20 pupils per school will be included in the evaluation. Schools will supply details on all pupils in the selected Y1 class and 20 will be randomly selected by the evaluation team. Assessing more pupils provides negligible gains in statistical sensitivity and is therefore difficult to justify the additional one-to-one assessment costs.

Participation is conditional on compliance with the terms of the MoU, but all maintained mainstream schools with pupils in the appropriate age range can take part provided that they have not already used the Infant Language Link intervention. As the trial is supported by the DfE Accelerator Fund, the aim is to recruit 50% of schools from local authorities that are Education Investment Areas. Schools will be recruited by the developer. Pupils diagnosed with autistic spectrum disorders (ASD), selective mutism or global learning difficulties cannot be included in the evaluation as the intervention is not designed to support children with these needs.

Sample size calculations

The design is a 2-level clustered RCT. In calculating the Minimum Detectable Effect Size (MDES), the smallest effect size that could be detected as statistically significant (often set as p<0.05) with a statistical power of 80% or higher, our estimates are based on the following assumptions:

M_{j-k-2} - T-distribution multiplier assuming a two-tailed test with a statistical significance of 0.05, statistical power of =0.80 and J-K-2 (164) degrees of freedom

R_i - Participant (pupil) level pre/post-test correlation of 0.75 (R_i²=0.56)

 R_c - Cluster (school) level pre/post-test correlation of 0.20 ($R_c^2 = 0.04$)

ρ - Intracluster correlation (ICC) of 0.20

j - Number of schools = 170

m - Pupils per school = 20

k - Number of cluster level covariates¹ = 4

P - Proportion of schools allocated to intervention group (P=0.5)

The participant correlation values are taken from Dimova et al (2020), which used a very similar primary outcome measure (Preschool CELF instead of CELF-5), and we have conservatively estimated the school level correlation at 0.20. The ICC reported at the analysis stage of Dimova et al (2020) was surprisingly high (0.35), so we have provided MDES estimates for a lower ICC (0.20) which is closer to the figures from the randomisation and protocol stages of that evaluation (0.15 and 0.12 respectively). This is also the default ICC recommended for attainment outcomes by the IES What Works Clearinghouse (2022:171). Calculations were performed in Excel using the formula set out in Bloom et al (2007) for two-level clustered randomised controlled trials. This allows covariates to be included at both individual (pupil) and cluster (school) level, which in turn increases sensitivity.

Equation 1: Minimum Detectable Effect Size in a two-level clustered RCT

MDES =
$$M_{j-k-2} \sqrt{\left(\frac{\rho(1-R_c^2)}{P(1-P)J}\right) + \left(\frac{(1-\rho)(1-R_i^2)}{P(1-P)Jm}\right)}$$

ITT sample

With a clustered design there are negligible gains from increasing the number of pupils per school beyond a certain point. As mentioned above, the study sample will therefore be restricted to 20 pupils randomly selected from a single class from each school. Schools will

¹ Whether a school is in an Education Investment Area, uses another relevant intervention, uses external speech and language support at least once each half term, or uses such support but less frequently than every half term.

submit a list of all pupils in the class to the evaluation team, and the 20 will be sampled from each list prior to baseline testing in Autumn 2023/24. Intervention schools are free to provide the programme to the entire cohort but any delivery to pupils not in the selected class would fall outside of the evaluation.

Subgroup analysis will be conducted on:

- Pupils selected for additional support in intervention schools. A comparison sample from control schools will be identified using scores on the baseline assessment.
- Pupils eligible for free school meals obtained from the NPD, as is required for all EEF trials.
- Pupils with English as an additional language, as the developer provides specific advice for supporting these pupils, recommending that they are assessed for their fluency level. We will request this data and explore options for sensitivity analysis.

MDES estimates

Table 1 summarises the MDES estimates for our central design based upon the estimates and assumptions outlined above for a sample with 170 schools (20 pupils per school) to reflect the recruitment target and the minimum class size eligible for the trial. The MDES estimate is 0.20 (and is the same for 160 schools, falling to 0.21 for 150 schools and 0.22 for 140 schools). For the FSM subgroup, estimated at five per school, the MDES is 0.22 for 170 schools.

In the event of 10% attrition at school level, the MDES would be reduced to 0.21. This would remain applicable provided that pupil level attrition stays below 20% (leaving at least 15 pupils from each school in the analysis sample). With no attrition at school level, the MDES would remain at 0.20 if 13 pupils per school are present in the analysis sample.

Table 2: Sample size calculations

		OVERALL	FSM
Minimum Detectable Ef	Minimum Detectable Effect Size (MDES)		0.22
Pre-test/ post-test	level 1 (pupil)	0.75	0.75
correlations	level 2 (school)	0.20	0.20
Intracluster correlations (ICCs)	level 2 (school)	0.20	0.20
Alpha		0.05	0.05
Power		0.80	0.80
One-sided or two-sided	?	2	2
Average cluster size		20	5
	Intervention	85	85
Number of schools	Control	85	85
	Total	170	170
	Intervention	1700	425
Number of pupils	Control	1700	425
	Total	3400	850

Outcome measures

Primary outcome

As the intervention aims to improve pupil expressive and receptive language, a primary outcome incorporating measures of both dimensions will be used. This will comprise the two Pearson CELF-5 subtests that are most relevant to this intervention (sentence comprehension, scored on a 0-26 scale, and linguistic concepts, scored 0-25), and the Renfrew Action Picture Test, which has two parts (information, scored 0-41, and grammar, scored 0-39). The intention is to combine these measures into a latent language variable using structural equation modelling, as per the approach used in the recent PACT and NELI evaluations (Dimova et al, 2020; Menzies et al, 2022). The original EEF NELI trial used a different method of combining language assessment scales, standardising and summing the constituent scores, and this approach will also be adopted as a sensitivity analysis for the main ITT sample. Further details will be specified in the Statistical Analysis Plan, to be published three months after randomisation.

<u>Amendment May 2024:</u> after exploring the creation of a combined baseline measure through structural equation modelling, it was decided that combining the four assessment scales into a primary outcome measure using a different method would be preferable. The approach adopted in Sibieta et al (2016), where the separate scales were each converted into z scores before being summed and standardised again, will now be used to form the primary outcome measure. Further detail on the process for reaching this decision is presented in the SAP.

All outcome data will be collected during June/July 2024. Assessments will be administered in school by researchers employed by the evaluation team. The intention is to recruit speech and language therapists with experience in administering language assessments. All test

administrators are required to attend a half-day training delivered by the evaluator, which consists of practical demonstration and practice of the CELF and RAPT. This is expected to improve consistency between the different testers, who will carry out data collection in person at participating schools and record their marks electronically before posting all completed test papers back to the evaluation team. As testers are being recruited on the basis of their professional qualifications and experience, they are likely to be highly competent. Quality assurance processes to ensure reliability will include moderation of a sample of 5% of returned test papers and the evaluation team will ensure daily contact to identify any issues.

Secondary outcomes

The two CELF-5 subtests used for the primary outcome will be analysed separately as secondary outcomes. The Renfrew Action Picture Test also comprises two components (information, scored 0-41, and grammar, scored 0-39) which will be analysed separately as secondary outcome measures.

Baseline measures

For each analysis, the assessment data collected post-intervention will be used as the outcome and data on the same measure collected at pre-intervention will be used as the baseline covariate. All baseline assessments will be conducted in schools in September/October 2023.

Compliance

Table 3: Compliance indicators

Activity	Full compliance Part compliance			
Training	SENCo attends 3 initial sessions; teacher and TA attend 2 sessions each			
Initial pupil language screening	Delivered to all pupils in participating class at start of intervention period			
Targeted groups	Delivering 6/8 sessions ² in a listening group, and 8/8 sessions in two others 6/8 in listening group one other group			

Analysis

Multilevel linear regression models will be constructed for the primary outcome, with pupils clustered into schools. A measure of language and communication combining the Pearson CELF-5 (sentence comprehension and linguistic concepts subtests) and the Renfrew Action Picture Test will be used as the baseline covariate for analyses of the primary outcome, which will be the same as the outcome measure (but collected at pre-intervention). The first model will only include the school level group identifier (an outcome only model) and will supply the unconditional variance figure used to calculate the effect size. The second model will add the baseline covariate at the pupil and school levels³. The final model will also include the randomisation stratifiers (geographical area, use of similar interventions, use of external speech and language therapy services). This final model will form the headline ITT impact analysis for the primary outcome.

Secondary analyses will focus on the impact of Infant Language Link for disadvantaged pupils, as defined by the NPD variable EVERFSM_6, and pupils identified for additional support in intervention schools. The same models used for the headline ITT analyses will be used here. Further exploratory analysis will be undertaken for pupils classed as EAL. The analysis will follow the same procedures as for the headline primary outcome analysis.

For each model, the coefficient of the school-level dummy variable used to distinguish 'intervention group' pupils within the schools who will receive the Infant Language Link programme from 'control group' pupils will be converted into Hedges' g effect size statistics with 95% confidence intervals.

The impact analyses will examine missing data in the outcome and explanatory variables and consider whether it is reasonable to assume that the missing data are random. A multilevel logistic regression model with a binary outcome identifying when outcome data is missing (=1) or not (=0) and the same covariates as the headline ITT model will be estimated to examine any patterns. This model will then be replicated with only participants at schools that took part in the outcome testing, to focus on pupil level attrition.

² Within the groups each session is rated as effective, partially effective, or not effective. These are then aggregated to work out an overall outcome for the group. We have a threshold of 6/8 set for attendance at a minimum number of sessions for each group otherwise the overall outcome is not accurate.

³ These will be centred so that the school level will be centred on the mean for all schools and the pupil level will be centred around the school mean.

Longitudinal follow-ups

KS1 tests for Y2 pupils are becoming non-statutory after 2023, yet some schools may continue with the tests for internal assessment purposes. The feasibility of follow up analysis using KS1 results data will be explored by asking schools about their plans. If more than half of schools are expecting to use KS1 tests in 2025, they will be asked to record the marks for Reading and GPS and share that data for follow up analysis. This will be agreed with schools at the start of the trial should a sufficient number indicate that they will run KS1 tests in 2025, when the study cohort will be in Y2.

Implementation and process evaluation⁴

IPE methodology

The aim of the IPE is to understand the barriers and enablers to implementation fidelity of the ILL intervention and to explore some of the causal assumptions identified through the agreed logic model (see Appendix A).

The IPE methods and questions are also designed to complement the compliance indicators as they explore the way the training is experienced by staff at the school, the perceived effectiveness of the screening tool, the provision of targeted group interventions, the delivery of classroom strategies, improvement targets and the completion of progress measures.

IPE Research questions

RQ1: To what extent was ILL implemented with fidelity and as intended:

- Have teachers, TAs and the SENCO attended the training sessions?
- o Have teachers made use of the ILL Helpdesk for implementation support?
- Have teachers used the screening assessment to screen all children in the class and identify pupils requiring support?
- o Have teachers implemented the whole class strategies in every lesson?
- Have TAs delivered the targeted intervention sessions (8 sessions in a listening group, and 8 sessions in two other groups)? Have pupils selected for targeted support been attending as per agreed compliance thresholds?
- o Have progress measures been completed and targets set for improvement?
- What is the uptake in other year groups and other classes in Y1 beyond the compulsory Y1 class?

RQ2: To what extent does the intervention, including the training and materials, improve teachers' and TAs' understanding and skills around oral language development?

RQ3: To what extent does the intervention, including the use of the standardised screening assessment, help teachers to identify pupils requiring support?

RQ4: To what extent does the tiered approach to the intervention support children's speech and language development? Are there particular challenges or benefits for specific groups (EAL, disadvantaged pupils)?

RQ5: What evidence is there that schools have changed their speech and language teaching and learning practices in response to the intervention, compared to business as usual?

RQ6: What contextual factors at school, practitioner and pupil level impact on the implementation of the programme?

RQ7: Are there any unintended consequences of the programme?

⁴ Please follow the principles detailed in the <u>Implementation and Process Evaluation Guidance (2019)</u>.

Table 4: IPE research methods

Research method	Data collection method	IPE dimension	Research Question	Sample size and sampling criteria	Data analysis method
Pre- intervention survey	Online questionnaire	Context/ moderators	RQ1,2,3,5	All schools; N = 170 teachers, 170 TAs	Summary statistics
Post- intervention survey (separate versions for intervention and control schools)	Online questionnaire	Fidelity , Quality, Dosage, Perceived impact, Reach , Context/ moderators	RQs 1 to 7	Intervention schools; N=85	Summary statistics
Interviews	Face to face individual semi-structured interviews, voice recorded	Fidelity , Dosage, Quality, Reach , Responsivene ss, Perceived impact, Context/ moderators	RQs 1 to 7	Intervention schools (n=10) Teacher, TA and senior leader	Protocol deductive coding; inductive causation coding; pattern coding
Observation (classroom)	Semi structured, non- participant observations	Fidelity Quality Responsivene ss	RQ1,4,5	Intervention schools (n=10) One targeted session and one whole class session observed	Protocol deductive coding; inductive causation coding; pattern coding
Observation (training)	Semi- structured observations of training sessions	Fidelity Quality Responsivene ss	RQ1	2 training sessions	Protocol deductive coding
Monitoring data analysis	Data on delivery collected from schools by developer	Fidelity Dosage Reach	RQ1, RQ4	All intervention schools	Summary statistics

Research methods

The IPE will comprise the following:

- 1. Evidence review and early discussion with stakeholders to build an evidence-informed logic model and agree data collection methods. This takes place during the set-up phase but is revisited prior to reporting, and ensures the study is informed by the relevant policy developments and recommendations on SLCN and SEND as well as by the literature on existing provision of speech and language support in school contexts.
- 2. Observations of training and review of teacher guidance and programme materials by the evaluation team to examine content, delivery format, and engagement with a view to exploring the implications for skills and understanding through subsequent data collection. This will also be used to identify areas of the programme which are emphasised by the development team during the training and specific advice given to teachers and TAs on ways of delivering the four components inherent to ILL. Findings will be used to refine the observation and interview schedules to be used during school visits in the spring term (see diagram 'Timing of methods').
- 3. **Pre-intervention online surveys** with teachers and TAs in both control and intervention schools. These surveys will be used to gather information on usual practice/ business-as-usual (BAU). Information on the use of any other relevant interventions, common programmes and practices will be gathered. The pre-intervention survey will address the following IPE research questions:
- **RQ1:** Information will be collected on whether the school systematically monitored and evaluated pupils' progress in speech and language development prior to the intervention. This will allow us to also examine RQ5, change in practice.
- RQ2: Questions will examine teachers' understanding, skills and confidence relating to children's oral language development prior to the intervention. This data can be compared to data gathered through the interviews and post-intervention survey.
- RQ3: Questions will be included on the current methods used in each school to identify
 children needing support with speech and language and the perceived effectiveness of
 these methods. These responses will be compared to data from the interviews and postintervention survey examining the perceived effectiveness of the ILL standardised
 screening assessment tool.
- RQ5: The pre-intervention survey will provide data on current teaching and learning
 practices, relevant internal policies, internal support for speech and language, ways of
 monitoring children's progress, barriers to accessing support, frequency of use of SLCN
 strategies in teaching. This data will then be compared to data from the post-intervention
 survey and interviews, identifying specific examples of change from BAU in speech and
 language related teaching and learning practices resulting from the intervention.
- 4. **Post-intervention online surveys** in intervention schools with teachers, TAs and the senior leader involved in overseeing the intervention will be used to gauge how closely the programme delivered followed the intended treatment model as defined in the ToC (fidelity). Data will be collected on the number of sessions delivered, including universal sessions, small group sessions and individual interventions as stated in the ToC (dosage).

Questions will also be included on how well the different components of the intervention were delivered (quality). These responses will be triangulated with qualitative data from

observations and interviews – both interviews and questionnaires will explore teachers' and TAs' perceptions of how well different components worked and were delivered, while the observation data will provide evidence of these assertions in practice. The post-intervention surveys will also explore teacher, TA and senior leader perceptions of whether the outcomes of the programme detailed in the ToC have been achieved (perceived impact). These responses will also be triangulated with qualitative data from the interviews, focussing on perceived impact.

Quantitative data will be collected on the rate and scope of participation in the programme (numbers of teachers, TAs, senior leaders and children taking part in the programme) (reach). This data will be triangulated against responses to the semi structured interviews, confirming the rate and scope of participation. Finally, the post intervention surveys will collect data on any contextual factors impacting on the delivery of the programme – for example, whether a focus on the ILL programme was affected by the need to prepare pupils for the Phonics Screening Check; issues relating to staff turnover or availability; concurrent Ofsted inspection, possible (although unlikely) Covid restrictions (context/ moderators). Similar questions will also be asked in the semi structured interview, triangulating the data obtained in the post-intervention survey.

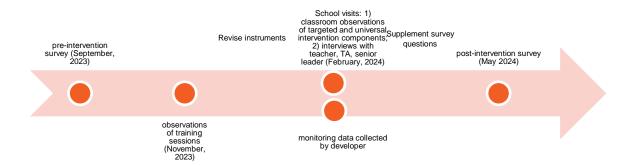
- **5. Post-intervention online surveys in control schools** sent to a senior leader overseeing the involvement of the school in the programme. This survey will focus on establishing whether there is evidence of **contamination** for example control schools increasing provision for SLCN during the time of the intervention running in intervention schools, or accessing another relevant programme on speech and language during this period. The survey will also examine the dimension of **context/ moderators** exploring whether any broader issues (for example change in policy or regulations, Covid-19 disruption) have led to adaptations to usual provision for speech and language in the school.
- **6. School visits** carried out by the evaluation team to understand fidelity to the programme, to ascertain influences on implementation and the extent to which implementation is aligned with programme design. Purposive sampling will be used to identify 10 "case study" schools and aiming for an even geographical spread, with some schools located in Education Investment Areas and some that are not. A mixture of schools that access external speech and language support and those that do not will be sought. On each visit, the evaluation team will conduct:
 - out in a targeted intervention session and in a whole class session, to explore evidence of fidelity of implementation (RQ1) and answer RQ4, focussing on the effectiveness of teacher and TA use of the Break it Down, Explain Clearly, Check as You Go and Keep it Visual strategies. Observation data will be collected through field notes captured in a semi structured observation schedule, with a particular focus on pupil engagement with the strategies, their ability to respond to the tasks set, their use of expressive and receptive language in response to stimulus from the teacher or TA. The observations will enable an understanding of the effectiveness of the tiered approach to the intervention in supporting children's speech and language development (RQ4). In addition to providing data on RQ4, classroom observations will explore whether there has been a substantial change in teacher and TA practice in supporting children with speech and language development (RQ5). This observational data will be triangulated with teacher and TA interviews and survey responses.

- Semi structured interviews with staff involved in the implementation of the ILL programme. Three interviews per case-study school (30 interviews in total) are planned, involving the TA and the teacher with direct involvement with ILL programme and the member of the leadership team who has attended the training and has overall responsibility for the programme within the school. Participants will be interviewed separately to allow for differentiation in the focus of discussion (whether this is on the whole class intervention, or the targeted component, or on any challenges and enablers of implementation in the school). Specific questions will be included in the interview schedules for teachers and TAs regarding the use of the ILL teaching and learning approach within the targeted and the whole class components of the intervention, addressing RQ4. Teachers and TA interviews will also explore the use of carryover activities which facilitate continuity of the use of strategies, activities, and topic work from the targeted intervention to the whole class sessions. This will highlight the connections made between the targeted and universal components of the intervention (RQ4). The leadership team member interview will include questions on how they oversee delivery the programme and mechanisms for tracking the pupil progress in speech and language development (RQ4 and RQ5). Interview questions will further explore each of the research questions listed above (RQs 1 to 7) and examine the corresponding IPE dimensions of fidelity, dosage, quality, reach, responsiveness, perceived impact and context/ moderators. Qualitative interview data on each of the IPE research questions will be used to triangulate responses from the quantitative post intervention survey data in intervention schools and the data collected through semi structured observations. The interviews will be voice recorded following informed consent from each individual participant.
- **7. Analysis of monitoring data.** The developer collects information from schools on the implementation of the intervention. Some of this is being used in determining compliance to the intervention, which is part of the impact evaluation. We will present descriptive statistics on key variables relevant to fidelity and dosage as part of the IPE. This will include whether schools are recording progress measures and setting targets for improvements, and also the number of targeted sessions delivered.

Analysis

A mixed methods multi-phase design (Borglin, 2015) will be used to collect and analyse the IPE data, comprising of pre and post intervention surveys, observations of training sessions, classroom observations, semi structured interviews and monitoring data. The multi-phase design will allow for qualitative and quantitative methods to be deployed concurrently as well as sequentially. The methods of data collection will be mixed during data collection, allowing for insights from the observation of the training sessions to shape the design of the observation schedule and semi-structured interview questions (see Figure 1). Mixing during data collection will also allow for initial insights from the classroom observations and interviews to inform the design of the questions in the post-intervention survey for intervention schools (for example, more specific questions can be asked about contextual factors, once interviews have been carried out).

Figure 1: Timing of IPE methods



Mixed methods analysis

Sequential, parallel and simultaneous data analyses will be applied in the process of mixing qualitative and quantitative data within the IPE. During ongoing fieldwork, sequential data analysis will be applied, to allow for insights from one method analysis to inform the design of the next (Borglin, 2015). There are two examples of this in the proposed IPE design. Firstly, the observation of training sessions will inform the design of the observation and semi structured interview schedules; secondly, the preliminary analysis of observations and interviews will inform the design of some of the questions for the post-intervention survey aimed at intervention schools. Following this initial stage of sequential data analysis, parallel data analysis will be applied where numerical data from the pre- and post- intervention surveys and textual data from interviews are analysed separately, but the findings are integrated during the interpretative stage.

Classroom observations will yield both qualitative and quantitative data. Simultaneous data analysis will be used in the case of observation data to enable a holistic interpretation of the teaching and learning interactions observed. Findings from the observation dataset will then be integrated with the broader IPE findings during the interpretative stage.

Analysis of quantitative data

Numerical data collected through school staff surveys and through monitoring information gathered by the developer in the course of delivering their intervention will be analysed through descriptive statistics. For survey items relevant to both intervention and control schools, such as those relating to teaching practice or confidence, crosstabulations will be used to present the results. Multivariate statistical methods will not be used in the IPE. Findings from the pre-intervention survey may be used to inform the design of fieldwork interview schedules and the fieldwork findings may inform post-intervention survey design. The IPE section of the final report will be structured thematically according to the research questions, which will facilitate the presentation of data collected from different research methods in an integrated manner.

Analysis of qualitative data

A mixed methods approach will be used to analyse the data collected through interviews and observations of universal and targeted group interventions.

The qualitative analysis of training session observations, semi structured interviews and classroom observations will follow the two-stage coding approach from Miles, Huberman and Saldaña (2014), consisting of a first cycle of initial coding and a second cycle of pattern coding and analytic memoing. In both cycles the approach to coding will be mixed, allowing for deductive and inductive coding as follows:

- deductive coding, which is essential for exploring the logic model and causal assumptions, focussing on the dimensions of fidelity, dosage, reach, quality, reach, responsiveness, perceived impact and context.
- data-driven inductive coding, to allow researchers to listen to participants' subjective
 experience of implementing the intervention in practice. Inductive coding will be
 essential in understanding the IPE dimensions of fidelity, quality, responsiveness,
 perceived impact, reach, context/ moderators and any discussion concerning the
 perceived challenges and benefits of implementing the programme.

Coding will be carried out in two cycles, with the first cycle involving both inductive and deductive coding and allowing for descriptive categories to emerge, followed by a second cycle which will involve categorising and integrating the codes into themes and constructing concepts from the categories (Saldaña, 2021).

First cycle coding

Based on the deductive coding and theme development approach outlined in Crabtree and Miller (1992) an initial template of codes will be developed, also known as protocol coding (Miles, Huberman and Saldaña, 2014). The template of codes will be based on categories central to the evaluation and emerging from the agreed logic model and its causal assumptions. It will also be based on insights gained from the observation of the training sessions. The template of codes will be used to analyse data from:

- semi-structured interviews with teachers, TAs and leadership team
- observations of targeted and universal sessions
- open-ended questions from the post intervention surveys

This approach is considered suitable when the analysis starts with an initial conceptual model (Miles and Huberman, 1984) which in this case is the agreed logic model for the Infant Language Link programme evaluation and its causal assumptions. Data will be coded using the agreed codebook and triangulated across the qualitative datasets. Documents from all relevant datasets will be imported in NVivo which will make visible the appearance of codes in more than one dataset. In each case evidence supporting the code will be sought from more than one dataset and where this is found this will increase confidence in the concept or finding (Clark et al, 2021). Multiple instances of the code found across more than one dataset will indicate that this code could be developed into a coding category or could form the basis of a key finding to be developed further into a broader theme. It is expected that two members of the evaluation team will be involved in coding the data. Using the preliminary codebook supports testing for intercoder reliability and for critical examination of the appropriateness of the codes (Miles and Huberman, 1994).

Example of first cycle protocol deductive coding:

	Exploring causal assumption 4: Receptive language screening will identify students with below average receptive language skills for school staff to target with the intervention.			
SURP ID	SURP ID the screening tool helped identify children that staff were unaware required SLCN support			
EXP ID	the screening tool helped identify children that staff were aware already required SLCN support			
impact on classr	Exploring causal assumption 6: Four core quality first teaching strategies will have an impact on classroom practice enabling teaching staff to create a communication friendly environment, supporting students with language difficulties to access teaching.			
BID TF break it down strategy using talking frames used in lesson				
EC KV explain clearly by discussing the meaning of key vocabulary used in lesson				

Protocol coding will be followed by causation coding which explores causal beliefs by participants, as well as aspects such as conditions, contexts and consequences. This type of coding is inductive and data driven and will allow for insights into aspects such as: the perceived challenges and benefits of implementing different aspects of the Infant Language Link intervention; perceived changes made to practice; decisions regarding the programme's reach and understanding the contextual factors affecting programme delivery.

Second cycle coding

Second cycle coding will involve the application of pattern coding which will condense the large number of first cycle codes into pattern codes. Pattern codes will help summarise the first cycle coding into categories/ themes, causes/explanations, relationships between people and theoretical constructs (Miles, Huberman and Saldaña, 2014). Pattern coding will also enable visual representations of the data through matrix and network displays.

In second cycle coding, the codes identified through first cycle coding will be connected through a process of discovering themes and patterns in the data (Feredey and Muir-Cochrane, 2006). This will be guided by the IPE research questions (RQs 1-7) and allow insights and themes to emerge on the basis of the deductive and inductive coding carried out in the first cycle.

Both cycles of coding will examine the extent to which the programme outcomes have been achieved, the key enablers and barriers and evidence of the relationships between specific inputs, outputs and outcomes. Matrix and network displays (Miles, Huberman and Saldana, 2014) can be used to visualise these relationships in the data and to support inductive inference. Nvivo's relationships and matrix building tools will be utilised.

To support the dependability and trustworthiness of the qualitative data, a further stage of corroborating coded themes (Feredey and Muir-Cochrane, 2006) will be applied aiming to confirm the thematic findings. The resulting thematic findings will be compared and corroborated against the earlier stages of first cycle coding to ensure that interpretations from the latter stages of coding represent the original data and earlier stages of coding.

Pattern coding will lead to the development of middle level theory (Rubin and Rubin, 2012) aiming to inform potential logic model redevelopment and concerning the implications of the IPE findings regarding the value of the ILL intervention to improving children's oral language skills and supporting teachers and TAs in developing communication friendly classrooms, supporting all children's access to learning.

Cost evaluation

Delivery costs will be calculated using data provided by the Infant Language Link developers. This will be conducted in line with EEF cost evaluation guidance to produce per pupil costs over three years. Specific items to be considered will include time for teacher training and preparation (but not delivery as this takes place during normal lessons) and costs of learning materials provided to each intervention school at the start of the trial. Please see Appendix for details of the amount of time the developer believes schools should allocate to training and preparation. The post-intervention survey will be used to ask schools if their experience of the programme is consistent with these figures.

Ethics and registration

Schools will receive a participant information sheet that must be sent to the parents/carers of all pupils taking part in the trial before their data is shared with the evaluation team. This will be forwarded to schools in the Summer term of 2022/23. It will contain details about the intervention and the evaluation, a statement on data protection along with links to further documentation on data sharing and other relevant matters, and a slip for parents/carers to return to the school if they wish for their child to not take part in the evaluation.

The trial is publicly registered at: https://www.isrctn.com/ISRCTN60336419

Data protection⁵

SHU and SLM are independent data controllers as both are collecting data from schools. All data will be held on secure organisational networks The processing of personal data (pupil identifiers) is defined under GDPR (Article 6 (1e)) as a task in the public interest. Special category data (FSM and EAL status) will be processed for the purpose of research under GDPR Article 9 (j). Further details are published in a trial specific privacy notice: https://www.shu.ac.uk/sheffield-institute-education-research/projects/infant-language-link.

After the evaluation is complete, SHU will retain participant data in anonymised form for research and knowledge exchange purposes, including academic presentations or publications, for five years after the publication of the final project report. SHU will remain as a data controller for this period. SLM only retain personal data at specific request of schools.

SHU will also submit project data to the EEF data archive once the final report has been published. At this point, EEF becomes a data controller, and EEF's data contractor for the archive becomes a data processor.

Evaluation data will be linked with information about the students from the National Pupil Database (NPD), and shared with the Department for Education, the EEF's archive manager and, in an anonymised form, with the Office for National Statistics, the UK Data Archive and potentially other authorised research teams. Further matching to NPD and other administrative data may take place during subsequent research. Personal data will not be transferred or stored outside of the EEA at any point.

Personnel

Evaluation team

Dr Martin Culliney, is Senior Research Fellow at the Sheffield Institute of Education (SIOE), Sheffield Hallam University. He will act as principal investigator and impact

⁵ Please see the Data Protection Statement for EEF Evaluations.

evaluation lead. Martin is currently leading the EEF English Mastery evaluation and is lead author on EEF reports for the literacy interventions Integrating English (2019) and REACH Primary (2021).

Dr Ester Ehiyazaryan-White is a Senior Lecturer in Childhood and Early Childhood in SIOE and will lead the IPE. She worked on the IPE of the EEF of Integrating English evaluation and was also part of the project team on the Digital Literacies in the Early Years European Project (DigiLitEY). Her research interests focus on early literacies, multilingualism and positive identity development.

Dr Dieuwerke Rutgers is Research Fellow at SIOE and will support the IPE. Her research specialises in the cognitive, psychological, and social effects of multilingualism and language development. At SIOE, she is currently part of a team of researchers on the EEF Regional Implementation Leads in Bristol pilot evaluation.

Dr Karen Daniels leads developments in English across Primary and Early Years Initial Teacher Education in SIOE and will act as advisor to the IPE. Her research interests include literacy pedagogy and the social, emotional and cognitive dimensions of reading. She led the IPE strand of the EEF REACH Primary trial and is a co-author of the evaluation report (2021).

Sean Demack is a Principal Research Fellow and Deputy Head of the SIOE research centre. He has extensive experience in the design and analysis of educational RCTs. Sean directed the EEF Realistic Maths trial and will act as statistical advisor.

Delivery team

Derry Patterson is the Lead Speech and Language Therapist for Speech Link Multimedia Ltd. She has extensive experience of delivering speech and language therapy services and training to mainstream schools and alternative provisions. She is the author of Speech Link, Infant Language Link and Junior Language Link programmes.

Louise Burton is a highly specialist Speech and Language Therapist. She has worked in mainstream primary and secondary schools as a consultant and is the co-author of the Ultimate Guide to SLCN. She leads research for Speech Link Multimedia Ltd and will lead the delivery of Infant Language Link for this project.

Yin Collighan is a specialist Speech and Language Therapist with experience of working in mainstream and specialist primary and secondary schools for NHS and local council services. She has worked on a range of projects, most recently as an evaluator for the Hanen Learning Language and Loving It programme. Yin will be assisting with recruitment of schools and evaluators and delivering training to the schools for this project.

Risks

Risk	Mitigation	Adjusted risk
Recruitment problems	Recruitment started seven months before baseline test period. Wide range of areas targeted. Control schools offered payment as usual in EEF trials.	Medium

Not enough testers recruited for testing or testers drop-out	Dedicated administrative staff in constant contact with schools. Aiming to recruit large pool of test administrators across England to collect data.	Medium
Low quality of test administration	Testers are qualified speech and language therapists with understanding of the assessments used.	Low
High level of schools incomplete assessment due to either tester or schools cancelling last minute	Test periods of six weeks should be long enough to arrange other visits. Pay rate provides good incentive for testers to turn up. Qualified professionals should be reliable. Schools know testing is non-negotiable condition of participating. Randomisation done after baseline testing.	Medium
Intervention not delivered with fidelity	Monitored through compliance data.	Low
Pupil/teacher attrition	Whole classes take part, so statistical sensitivity more affected by schools than individuals. Regular contact with schools should sustain engagement.	Low

Timeline

Table 4: Timeline

Dates	Activity	Staff responsible/ leading
Oct 22	Set-up meetings and IDEA workshop	All
Nov-Dec 22	Ethical approval Draft MoU, consent and information forms Design IPE instruments Evidence review	SHU
Feb-Jun 23	Recruitment (including school data collection)	Speech Link
Mar 23	Protocol Trial registration	SHU
Apr-Jul 23	Pupil data collection from schools	SHU
Jul 23	Pre-intervention teacher survey Training test administrators SHU	
Sep-Oct 23	Baseline testing	SHU
End Oct 23	Randomisation	SHU
Nov 23	NPD application	SHU
Nov-Dec 23	Teacher training/observations	SHU/Speech Link/schools
Dec 23	Statistical Analysis Plan	SHU
Jan-May 24	Intervention delivery	Speech Link /Schools
Jan-May 24	Conduct IPE school visits	SHU/schools
Jun-Jul 24	Outcome testing Post-intervention teacher survey	SHU/schools
Sep-Dec 24	Data analysis and report writing	SHU
Jan 25	Report first draft	SHU

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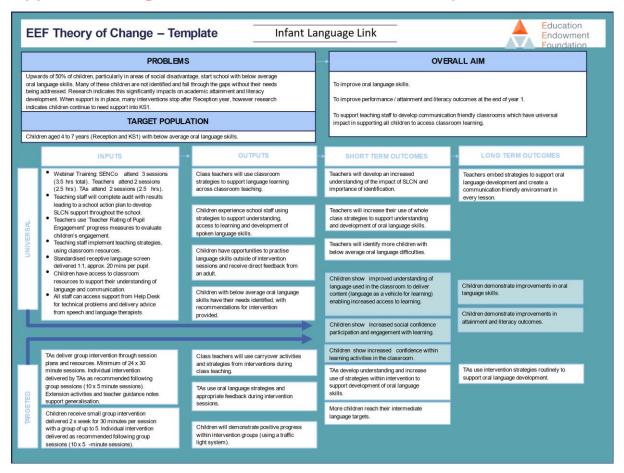
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Appendix A: logic model and list of causal assumptions



List of causal assumptions:

- 1. Teacher and TA understanding of the importance of oral language skills is improved by engagement in the training sessions.
- 2. Teacher and TA skills for supporting development of oral language are improved by engagement in the training sessions.
- 3. Teachers are motivated to change their practice through an improved sense of the importance of oral language skills.
- 4. Receptive language screening will identify students with below average receptive language skills for school staff to target with the intervention.
- 5. The language areas focused on in the assessment and development in the intervention are key functional areas of language for children in Reception and KS1 that are important in enabling them to access the curriculum.
- Four core quality first teaching strategies will have an impact on classroom practice enabling teaching staff to create a communication friendly environment, supporting students with language difficulties to access teaching.
- 7. Group and individual targeted intervention sessions delivered by TAs will improve children's oral language skills.
- 8. Use of the Infant Language Link whole school package in schools will result in significant improvement to children's oral language skills.
- 9. Improvements in oral language skills will translate to improvements in literacy and attainment.

Appendix B: cost evaluation

Table 5: Total time devoted by personnel for training and teacher cover

		Year 1		Year 2		Year 3	
		Number	Mean	Number	Mean	Number	Mean
		of	number of	of	number of	of	number of
		teachers	hours	teachers	hours	teachers	hours
Training	TA	1	2.5	N/A	N/A	N/A	N/A
	Class	1	2.5	N/A	N/A	N/A	N/A
	teacher						
	SENCO	1	3.5	N/A	N/A	N/A	N/A
Teacher	TA						
cover							
	Class						
	teacher						
	SENCO						

Table 6: Total time devoted by personnel for preparation and delivery

		Year 1		Year 2		Year 3	
		Number of	Mean number	Number of	Mean number	Number of	Mean number
		teachers	of hours	teachers	of hours	teachers	of hours
Preparation	TA	1	13	1	4	1	4
	Class	1	6	1	3	1	1
	teacher						
	SENCO						
Delivery	TA	1	12	1	12	1	12
	Class						
	teacher						
	SENCO	1	8		4		2
Assessment	TA	1	9	1	9	1	9

Appendix C: recruitment screening survey

- Name of school:
- 2. School URN:
- 3. Address:
- 4. Postcode:
- 5. Total number of pupils moving into year 1 in September 2023
- 6. Number of classes in year 1
- 7. Does your school have mixed year groups within your classes? Yes/No
- 8. Does your school currently use any programme/training/intervention designed to develop pupils' speech, language and communication skills? Please tick all that are used in your school. Infant Language Link/ WellComm/ Talk Boost/ NELI/ Language for Learning/ Elklan Training/ other ["other" boxes when ticked, allow you to add information.
- 9. How long has your school used these packages for? Enter the name of the package followed by the years
- 10. How many hours of SLCN intervention is delivered in your school currently using these packages? None/Less than 1 hour per week/ 1 hour per week/2-3 hours per week/ More than 3 hours per week.
- 11. Which year groups are these interventions delivered to?
- 12. Has your school previously used any different speech and language intervention packages that you no longer use? Yes/No
- 13. If yes, please state the name of the intervention package and reasons for discontinuing the intervention.
- 14. Does your school receive any support from external Speech and Language Therapy Services? Yes/No
- 15. If Yes, please describe the service provided in terms of who delivers the service e.g. NHS or independent practitioner.
- 16. How often do you access these services? Daily/Once per week/Once every half term/Once a term/Once a year/Other
- 17. Would your school be interested in participating in the project for a second year (2024/25)? Yes/no
- 18. Contact name
- 19. Contact email address
- 20. Contact role within school
- 21. Contact telephone
- 22. Please state where you heard about this project? EEF website/The Link magazine/From a colleague/Google search/Speech and Language Link website/other