STUDY PROTOCOL

Let's get talking together

FULL/LONG TITLE OF THE STUDY:

PLACES: Promoting Local Access to Children's Early language and communication Support

SHORT STUDY TITLE / ACRONYM:

PLACES

PROTOCOL VERSION NUMBER AND DATE: Version 1.0 31/01/2024

RESEARCH REFERENCE NUMBERS

IRAS: N/A Newcastle University Ethics

University Ethics:

Sponsors Number: NU014522

Funders Number: NIHR156329

This protocol has regard for the HRA guidance.

This study/project is funded by the NIHR Health and Social Care Delivery Research Programme (HDSR). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: ....

Date: ....../....../......

Name (please print): ....

Position: ....

Chief Investigator:

Signature:

Date: 28/03/2024

Name: (please print): Lindsay Pennington

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KEY STUDY CONTACTS

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Funder(s)	NIHR – Health and Social Care Delivery Research (HDSR)
Key Protocol Contributors	Lindsay Pennington, Cristina McKean, Tim Rapley, Tomos Robinson, Laura Ternent, Jochen Einbeck
Committees	Leadership Team Project Management Group Study Steering Committee PPI Advisory Group

STUDY SUMMARY

Study Title	PLACES: Promoting Local Access to Children's Early language and communication Support
Internal ref. no. (or short title)	PLACES NU014522
Study Design	Mixed methods in three case study local authorities: Data review, workshops, quantitative evaluation pre and post intervention, comparator analysis of retrospective routinely collected data, health economic evaluation of the intervention, feasibility and acceptability of the intervention, qualitative study of the experiences of families, carers, and health care professionals.
Study Participants	Children aged 0 – 3 years Parents Professionals from health, education and social care
Planned Size of Sample (if applicable)	Up to: 360 children (120 per local authority) 0 – 3 years with language and communication needs Further anonymised, routinely collected data from local authorities from a further 1140 children with language and communication needs (comparator arm)
Follow up duration (if applicable)	6 months post baseline
Planned Study Period	01/05/2025 31/12/2026
Research Question/Aim(s)	Can evidence-based early language interventions be tailored to fit local needs and strengths to widen access to services and reduce inequalities in children's language development?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Policy Research Programme, NIHR Central Commissioning Facility (CCF)	**£1,289,427.30**

ROLE OF STUDY SPONSOR AND FUNDER

Sponsor: Will oversee research governance and indemnity and assumes overall responsibility for the initiation and management of the study.

Funder: Will monitor and support the timely delivery of the contracted study, including approving all changes to the study protocol.

Neither sponsor nor funder has any role in the study design, conduct, data analysis and interpretation and manuscript writing.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Management and oversight of the study will be accomplished through four key groups:

1. **Leadership Team**
2. **Project Management Group**
3. **Study Steering Committee**
4. **PPI Advisory Groups**

1. Leadership Team

Professor Lindsay Pennington will have overall responsibility for the project, assisted by Professor Cristina McKean. This leadership team and the Project Manager will meet weekly via Teams to review plans and project management. A representative from the sponsor may be invited where applicable.

2. Project Management Group (PMG)

The full research team (all co-applicants) will meet monthly via Teams. Meetings will be chaired by Prof Pennington with support from the Project Manager. The meetings will be formally recorded, and minutes circulated to all project partners.

The main responsibilities of the PMG will be to:

- Monitor progress of work against milestones
- Review project outputs
- Monitor project risk management and contingency planning
- Determine and agree on any requested project changes
- Devise and monitor communication and dissemination plan

3. Study Steering Committee

The Study Steering Committee (SSC), chaired by Professor Doug Simkiss, will meet every quarter via Teams:

- Provide advice, through the Chair, to the Funder, the Sponsor, the Chief Investigator, the Host Institution, and the Contractor on all appropriate aspects of the project
- Check and facilitate progress of the study, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- Ensure that the rights, safety, and well-being of the participants are upheld
- Ensure appropriate ethical and other approvals are obtained in line with the project plan
- Agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments

4. PPI Advisory Groups

Four parent advisory groups (one national and one per site, 6-8 parents per group) will advise on study conduct and dissemination. The Parents Advisory Groups will meet four times annually which will include the training sessions and will be arranged in line with study requirements. The Parent Advisory Groups will convene at the beginning of the study and will review study documents, including participant information sheets and consent forms prior to ethics submission.

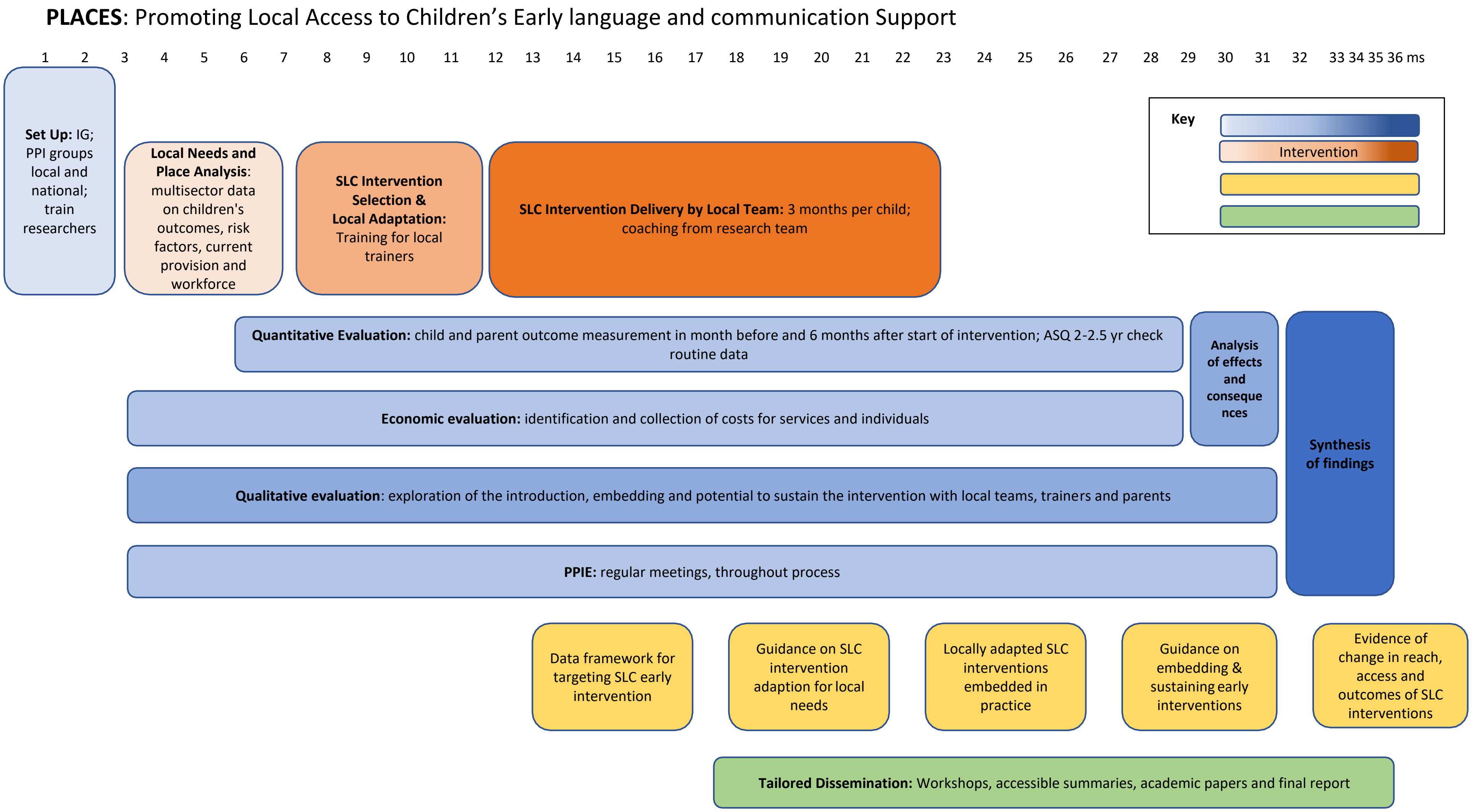
The Parent Advisory Groups will be inclusive and representative of families at risk of SLCN. The groups will continue to be involved for the duration of the study as per the original application. Two additional parents will be recruited to the Steering Committee that will supervise the conduct of the study.

NB: All project meetings may be escalated at the discretion of the Leadership Team as they see fit if the circumstances warrant doing so.

PROTOCOL CONTRIBUTORS AND CO-APPLICANTS

- Professor Lindsay Pennington (CI, Newcastle University)
- Professor Cristina McKean (Co-applicant, Newcastle University)
- Dr Laura Ternent (Co-applicant, Newcastle University)
- Professor Tim Rapley (Co-applicant, Northumbria University)
- Mrs Sue Welsh (Co-applicant, Northumbria Healthcare NHS Foundation Trust)
- Mrs Fiona Oliver (Co-applicant, Redcar and Cleveland Borough Council)
- Ms Phoebe Kent (Co-applicant, The Royal Wolverhampton NHS Trust)
- Mr Amit Kulkani (Co-applicant, Royal College of Speech and Language Therapists)
- Professor Jochen Einbeck (Co-applicant, Durham University)
- Mrs Louisa Reeves (Co-applicant, Speech and Language UK)
- Ms Victoria Gilroy (Co-applicant, Institute of Health Visiting)
- Dr Tomos Robinson (Co-applicant, Newcastle University)

Study Flow Chart: Figure 1.0



PLACES: Promoting Local Access to Children's Early language and communication Support

Set Up: IG; PPI groups local and national; train researchers

Local Needs and Place Analysis: multisector data on children's outcomes, risk factors, current provision and workforce

SLC Intervention Selection & Local Adaptation: Training for local trainers

SLC Intervention Delivery by Local Team: 3 months per child; coaching from research team

Quantitative Evaluation: child and parent outcome measurement in month before and 6 months after start of intervention; ASQ 2-2.5 yr check routine data

Economic evaluation: identification and collection of costs for services and individuals

Analysis of effects and consequences

Qualitative evaluation: exploration of the introduction, embedding and potential to sustain the intervention with local teams, trainers and parents

PPIE: regular meetings, throughout process

Synthesis of findings

Data framework for targeting SLC early intervention

Guidance on SLC intervention adaption for local needs

Locally adapted SLC interventions embedded in practice

Guidance on embedding & sustaining early interventions

Evidence of change in reach, access and outcomes of SLC interventions

Tailored Dissemination: Workshops, accessible summaries, academic papers and final report

STUDY PROTOCOL

PLACES: Promoting Local Access to Children’s Early language and communication Support

V0.1 31/01/2024

1 SUMMARY OF THE RESERACH

Research question

Can evidence-based early language interventions be tailored to fit local needs and strengths to widen access to services and reduce inequalities in children’s language development?

Background

Fourteen percent of two-year-olds in England do not have the language and communication skills expected for their age. Children from economically disadvantaged areas are most at risk. Speech, language, and communication needs (SLCN) bring profound risks of health, employment and social inequalities across the life-course. Early interventions can reduce these risks, but equity of access is affected by poverty, rurality, lack of access to digital resources and minority language background.

Aims and objectives

To identify the cross-sectoral, organisational, community and individual level factors that influence successful localised implementation of evidence-based early language interventions for young children at risk of SLCN.

To understand how multi-sector services can be configured within local authority areas to deliver high quality early language interventions to reduce health inequalities.

Objectives are to:

1. Create a framework to map the types and locations of data required to identify groups of children at risk of SLCN, current workforce and service access
2. Facilitate co-production of local adaptations to evidence-based early language interventions
3. Implement and embed locally adapted early language interventions for sustained provision
4. Evaluate the reach, effects, costs, return on investment and implementation of the locally adapted interventions to families and providers
5. Create guidance for health, local authority and third sector services on how to select, adapt, implement, and embed evidence based early language interventions

Methods

Mixed methods design in three case study local authorities:

- Data review. Multi-sector service leads from Speech and Language Therapy, Health Visiting, Early Years, Family Hubs, Special Educational Needs and Disability (SEND) and parents share summary level routine demographic and language development data, descriptions of current provision; agree a target group of children at risk of SLCN underserved by current provision

- Workshops. Local team selects an evidence-based intervention from a menu of previously reviewed programmes. Lead practitioners and parents co-produce a localised version of the intervention tailored to local needs
- Local staff trained to deliver the intervention in their settings. Implementation with 120 0-3-year-old children at risk of SLCN from local target group

- Quantitative evaluation: Children's language, quality of life and parent's wellbeing measured 6 months before localised intervention, baseline, 6 months after. Cost consequence analysis, contingent valuation study, and social return on investment. Process evaluation of feasibility and acceptability of localised targeted intervention.

- Synthesis of findings. Engagement with key stakeholders outside participating areas to create generalisable guidance

Timelines for delivery

Months1-11 Setup, data scrutiny, select target group, co-produce localised interventions. Months 12-23 Intervention delivery. Months 24-36 Complete evaluation, dissemination.

Anticipated impact and dissemination

If effective, localised interventions will increase the reach of SLCN support, positively impacting on young children's long-term outcomes. Generalisable guidance should allow implementation in other authorities and wider inequity to be addressed.

2 BACKGROUND AND RATIONALE

In England 14% of 2-2.5-year-olds do not

have the language and communication skills expected for their age (11). Children from economically disadvantaged areas are most at risk and prevalence reaches ~40% in the most disadvantaged populations (12). Speech, language, and communication needs (SLCN) bring profound risks of education, health, employment, and social inequalities across the life-course. SLCN is the most common type of special educational need and second most common need recorded on education, health and care plans. Early speech and language therapy (SLT) interventions can reduce these risks however provision of such support is scarce, difficult to navigate and often hardest to access for those who need it most (13, 14).

SLT services in the UK are in crisis. In England 82% of services have a backlog; >74,000 children are waiting to be seen (3). There are wide disparities between localities in annual spend per child (range 32p to £45 per year) (14). Social restrictions during COVID-19 have widened the gap in language skills for disadvantaged children and have further increased waiting lists (5). SLTs are reporting burn-out and dissatisfaction with the level of support they can offer families; large numbers of experienced SLTs are leaving the NHS (2). In response to rising needs many SLT services collaborate with the wider early years workforce across health, education, social care, and the voluntary sector to provide early intervention through awareness raising, training, enablement, and capacity building in the wider workforce (15). However early years provision is also experiencing disruption, with a 62% cut in council EY services spending since 2010 (16).

Early years SLCN provision in England is rarely comprehensive with equity of access being affected by issues such as poverty, rurality, lack of access to digital resources and minority language background (17, 18)

EVIDENCE EXPLAINING WHY THIS RESEARCH IS NEEDED NOW

Inequalities in SLCN

Language and communication difficulties follow the social gradient (19) and have negative consequences across the life-course. SLCN is associated with low literacy and educational attainment, limited employment, poor mental health, social exclusion, entry to the criminal justice system, and reduced health literacy (20-25). Hence child language and communication difficulties can be seen as both a cause and a consequence of social disadvantage with this clustering of vulnerabilities setting the stage for lifelong and intergenerational health inequalities (26). Yet only 50% of children with SLCN receive any form of additional support (27). Families living with social disadvantage are much less likely to seek and or be able to access support and public health interventions may inadvertently widen rather than narrow inequalities, as children and families with least needs benefit most (28, 29). and accessible provision of early language interventions for children aged 0-3 years capitalises on the period of greatest brain growth, realising larger benefits than later interventions, and creating a developmental cascade where early acquired skills (e.g., vocabulary knowledge) enable later skills (e.g., literacy) to be more readily acquired (30). Children’s response to early intervention also provides diagnostic and prognostic information that can be used to efficiently direct those who require them to targeted and specialist services. This efficient implementation of a tiered model enables children with milder difficulties to benefit from early interventions from the broader early years work force and those with more complex SLCN to receive appropriate levels of support sooner.

Current provision

The necessary services and community assets to provide such early preventative interventions are distributed across communities, health, social care, and education provision. Mobilisation of the wider workforce, beyond SLT, has the potential to increase the reach of language and communication support and capitalise on the specialist skills and knowledge of a wider pool of professionals (e.g., Health Visiting Teams’ delivery of the Speech Language and Communication strategy within the Best Start in Life NIHR156329 – PLACES programme (31). However, local models of support for children's language and communication are often complex, fragmented, and opaque. Family hubs aim to offer family-centred support rather than expecting families to navigate this complexity, but they are at differing levels of maturity and so many hubs are not yet meeting the needs of all families and children with quality of support for children’s language development identified as a particular concern for parents (17, 32). In the most recent DfE evaluation of the development of family hubs, there is a clear acknowledgement that it will take several years for most to become fully operational (32). The report identifies a number of key principles which will need to be put in place to enable hubs to operate successfully. These include joined up working across services and professionals, systems level thinking, better provision for families and children with Special Educational Needs and Disabilities (SEND), improved data sharing practices, and data-driven approach to identifying needs and measuring outcomes at the individual, area, and systems levels. Our study applies these principles to the provision of early SLCN support. We aim to develop transferable frameworks to guide the implementation of data driven, locally adapted, inter-professional, evidence-based interventions.

Furthermore, in a study within a project (SWAP) we will examine how early SLCN support can be inclusive of children with multiple long-term conditions who are likely to progress to a statutory assessment of their special educational needs and disability but who currently face long waits for specialist services (33).

Not only are many family hubs several years away from maturity, but also the reach and capacity of wider SLCN support varies considerably across and between local authority areas. Thus, gaps remain in provision and reach with underserved groups not in receipt of the support they need and potentially underexploited capacity in the multi-sector children's workforce that could provide SLCN support (18). The degree to which SLT services are embedded within these models is also highly variable and this in part may explain the fact that not all SLCN support provided to families is underpinned by research evidence (13).

A system level approach to audit and development of inter-agency SLCN provision in the UK has been developed (The Balanced System (34)), which focusses on predicting need based on indices of deprivation and mapping the workforce and models of provision against this predicted need. Our proposed study brings a more precise data driven approach using local outcomes and data on multiple SLCN risk factors to pinpoint those with SLCN who are currently underserved. PLACES also brings a unique focus on local adaptation of *specific* evidence-based interventions and on implementation processes required for their sustained adoption.

Speech Language and Communication are now core outcomes in the 'Best Start in Life' 0-5 provision led by Health Visiting (HV) Teams in England. However, this strategy recognises that HV offer is only one component of the broader inter-professional pathway which is required for effective SLCN provision (31). Furthermore, there are significant challenges to this provision due to the current crisis in the HV workforce with numbers of HV in England at an all-time low (1). PLACES aims to develop methods to leverage capacity across the children's workforce to support children with and at risk of SLCN, including the private, voluntary, and independent sector.

In recognition of the crisis in provision of support to children with SLCN and large waiting lists for children's specialist community SLT interventions, NHS England and the Department for Education are co-leading the Early Language Support for Every Child (ELSEC) programme. ELSEC will evaluate the provision of additional SLT workforce in early years and primary school settings in nine pathfinder sites across two years and is one of the programmes of work outlined in the recently published SEND and Alternative Provision Improvement Plan (33). ELSEC focuses on improving early identification and support for children with SLCN, through funding of innovative workforce models with emphasis on SLT and SLT assistants and aims to reduce the need for both specialist Speech and Language referrals as well as Education Health and Care Plans. There is clear complementarity between PLACES and ELSEC. PLACES brings a focus on the use of local data to identify under-served families, and on the implementation of specific locally adapted targeted interventions through capacity building in the wider children's workforce, to reduce the need for specialist intervention. ELSEC focuses on specialist provision. PLACES therefore has the potential to inform the implementation of ELSEC resource to yield maximum benefit and equitable reach in a tiered approach to SLCN support. ELSEC and PLACES leads have agreed to work collaboratively, sharing findings to ensure synergy, and added value in informing a graduated approach to SLCN.

Intervention Effects

Several recent systematic and thematic reviews demonstrate the efficacy of language interventions for children at risk of SLCN aged 0–3 years delivered universally or for targeted populations and report effect sizes of 0.4 to 0.6 (12, 35-39). Socio-cognitive theories of child language development (40) emphasise the importance of responsive interactions with caregivers for robust language development. A number of infant socio-cognitive skills are also crucial to early language development: the ability to share attention with adults, understand their communicative intentions and take turns in conversations.

Language is learned best in responsive social interactions between caregiver and infant where the language used by the adult is contingent on the child's attention and where the child is deploying these socio-cognitive abilities to infer meaning and maintain the interaction (41-43). Importantly, caregiver responsive, contingent interactions also facilitate the development of these socio-cognitive abilities and so are critical to robust language and communication development from the very earliest days of a child's life (44). Interventions harness these responsive adult-child interactions as active ingredients (45) enabling joint attention and the provision of language rich environments. Approaches can be broadly grouped into 1) resource provision (toys/books); 2) promotion of responsive interaction between children and adults (parents/early educators) in play and daily routines; 3) shared book reading activities and 4) direct instruction; with some in Early Years settings combining all four approaches. Drawing on those reviews Table 1. uses the TIDieR framework to identify key characteristics of an indicative sample of candidate effective interventions at universal and targeted levels of prevention (46). The studies in the table exemplify the range of dosage, agents, and methods of delivery present in the available evidence.

Reviews highlight the dearth of effectiveness studies and the challenges for implementation of this evidence with barriers related to dosage, fidelity, widening inequalities and both feasibility and acceptability for more socially disadvantaged families. For example, meta-analyses have demonstrated that promoting parent-child dialogic book-reading is more effective in socially advantaged than in socially disadvantaged families (28). This suggests that the underlying intervention active ingredients of responsive interactions, are effective but that barriers such as time, confidence and physical resources in socially disadvantaged families may make this specific approach unfeasible or unacceptable.

Table 1. Examples of candidate Universal and Targeted interventions using the TIDieR framework

Universal				
Intervention	**Age**	**(a) What**	**(b) Who; (c) How; (d) Where; (e) When and how much**	
Blocktivities (40)	18 – 30 months	(a) Parents/caregivers receive two sets of plastic blocks in the post and two newsletters describing games to play with them -“blocktivities”.	(b) Researcher (c) Posted resources (d) Family home (e) Set 1: One week after developmental check Set 2: 2 months later	
Encouraging ‘contingent talk’ (41)	11 months	(a) Parents/caregivers shown 10-minute video of caregiver -child contingent talk, told about its importance and given a leaflet. Asked to practice contingently responding to child 15 mins per day and complete diary. Follow up phone call reinforces messages and problem-solves.	(b) Researcher (c) Face-to face and phone call (d) Family home (e) 1x visit 1x phone call	
SPELL - Structured Preschool Efforts in Language and Literacy (42)	36 – 72 months	(a) Early Educators share books through a ‘soft-scripted’ sequence of instruction featuring before, during, and after reading activities and suggested language educators could use to support learning. Minimum 20 sessions to be effective	Educator Training (b) Researcher (c) Group (d) Not specified (e) 2 day 14 hour training.	Delivery with children (b) Early Years Educator (c) Group (d) Early Years Setting (e) 30 minute 2x weekly for 20 weeks
Universal or Targeted				
Shared or dialogic book-reading (36)	13 – 66 months	(a) Parents/caregivers trained to share books with their child using questioning and modelling +/- book gifting. Some support non-English speaking families to create home language books. Training involves modelling and coaching.	(b) Researcher (c) One-to-one (some via video); or group training plus one-to one (d) Early Years Settings, Health Centres and Homes (e) Between 3 – 18x 20 – 30 minute visits - 11 – 15 visits have best outcomes.	
Targeted				
Enhanced Milieu Teaching(51)	24 – 42 months	(a) Parents supported to use 6 language facilitation strategies in daily routines using a teach-model-coach-review structure	(b) SLT (c) One-to-one (d) Mix of clinic and Home visits (e) 4x 1 hour workshops; 24x 1 hour home visits; 2x per week over 14 weeks.	
Talk Boost (44)	36 – 56 months	(a) Educators trained in delivery of small group activities involving songs, books, addressing attention and listening, learning words and building sentences. Skills are linked to specific books which are shared with parents for home practice.	Educator Training (b) Researcher (c) Group (d) Not specified (e) 1 day 4 hour workshop	Delivery with children (b) Early Years Educator (c) Small group (d) Early Years Setting (e) 20 minutes 3x per week for 9 weeks
Happy Talk (45)	36 – 51 months	(a) Parent and educator training programs. Training involves sharing information about strategies and activities to promote language development plus coaching. Parents and settings receive visual supports and resources to support maintenance of behaviour change	Educator Training (b) SLT (c) Group and one to one (d) Early Years Setting (e) 4x 90 mins workshop plus 30 mins coaching over 10 months	Parent Training (b) SLT (c) Group and one to one (d) Early Years Setting (e) 12x 1 hour sessions over 10 months in blocks of 4

It is only through co-design that the detail of these barriers can be understood. A recent intervention co-design study found that a number of parents experienced book-reading interventions as patronising, whilst others felt they failed to engage their children's attention leading to experiences of failure and disruption in parent-child relationships (10). In both scenarios the barrier to engagement was not a lack of knowledge or motivation but the need to find more individualised contexts within which to promote responsive interaction. To ensure interventions achieve equitable outcomes work is needed to understand and address such implementation barriers (38).

'Scaling up' interventions found to be effective in research studies for delivery by educators in the 'real world' is also challenging (47). It is clear from reviews and large-scale trials that ensuring educators have the time, skills, knowledge, and support to deliver interventions to appropriate levels of fidelity and dosage is a real challenge (48, 49). Barriers include competing priorities, staff turn-over, and large class-sizes.

Lifting interventions 'off the peg' without consideration of contextual factors and their implications for implementation is therefore neither possible nor desirable and may contribute to the lack of evidence-based approaches in practice (38). Effective implementation requires adaptation to local service and workforce contexts and to the assets and needs of individual families and communities if interventions are to reach all children with SLCN and deliver equitable gains for families living with varying levels and types of social disadvantage (38).

3 AIMS AND OBJECTIVES

Research aims

The proposed research is designed to address the DHSC's areas of research interest of preventing poor health outcomes, reducing pressures on the NHS, and shaping and skilling the workforce to deliver future effective and efficient models of healthcare for local communities (50). Its goal is to improve access to and experience of services, and to improve children's health and wellbeing by applying systems thinking and taking a localised approach to inequalities in SLCN support and outcomes. Our research question is:

"Can evidence-based early language interventions be tailored to fit local needs and strengths to widen access to services and reduce inequalities in children's language development"

Objectives and outcomes

To identify the cross-sectoral, organisational, community and individual level factors that influence successful localised implementation of evidence-based early language interventions for young children at risk of SLCN.

To understand how multi-sector services can be configured within local authority areas to deliver high quality early language interventions to reduce health inequalities. Objectives are to:

1. Create a framework to map the types and locations of data required to identify groups of children at risk of SLCN, current workforce and service access

2. Facilitate co-production of local adaptations/tailoring to evidence based early language interventions by multi-sector professionals and parents
3. Implement and embed locally adapted early language interventions for sustained provision
4. Evaluate the reach, effects, costs, return on investment and implementation of the locally adapted interventions to providers and families
5. Create guidance for health, local authority and third sector services on how to select, adapt, implement, and embed evidence based early language interventions

4 STUDY DESIGN AND THEORETICAL FRAMEWORK

The study uses a mixed methods approach, with a sequential design in which the findings of a previous work package will be used to inform the following, to address systems problems in service provision through the application of systems thinking. It has been created with parents, early years leads, family hubs, SLTs, health visitors, nursery managers and support organisations. The study comprises six Work Packages (WP1-6) to address the five objectives (O1-5) (see Flow Figure 1.0), which use the cross-cutting methodologies recommended by DHSC (50). A deep dive into local provision of services and large-scale routine data will inform the identification of underserved populations and/or under-utilised workforce capacity and the selection of evidence-based interventions for local adaptation and implementation. Participatory co-design methods will drive local adaptation and implementation. A qualitative study will examine the experiences of families receiving the intervention and practitioners developing and providing it, to ensure that local adapted interventions and services are acceptable, and feasible. Quantitative analysis of language outcomes, quality of life and parental wellbeing will evaluate the clinical effectiveness of the intervention and the costs and consequences of its implementation.

Implementation science will help us understand how to make interventions work in different contexts and will inform the guidance we generate on applying the process of identifying need, targeting service change, designing, and implementing change in preschool SLCN intervention provision.

The research will focus on three local authorities - North Tyneside, Redcar and Cleveland, and Wolverhampton, which have been specifically selected to reflect the breadth of populations and complexity of service organisation in England:

1. All have high levels of social deprivation: 20-49% of households are in the lowest two deciles of social deprivation; 10-25% households are in the lowest decile
2. One area is mixed, with coastal towns of high deprivation and a large rural area; two are urban
3. Proportion of households with first language other than English 2.5-15%
4. Proportion of population from BAME backgrounds 3-39%
5. Proportion of 2-2.5-year-olds receiving developmental checks 70-94%

6. Population of 2-year-old children eligible for free childcare due to income and/or SEND 602-1414.
7. Proportion of eligible two-year-olds receiving free childcare 65-88%
8. Two areas have received government funding for their family hubs in 2022
9. One area has a written statement of action to improve their SEND services

Two areas have well established teams; one has several recently appointed leads across sectors. Service leads in the three areas from across early years, SEND, family hubs, health visiting, and speech and language therapy and their service directors are strongly committed to the research (see letters of support) and the opportunity to extend the reach of their multi-sector SLCN provision. The mixed-methods approach aligns closely with the targets of SEND and Alternative Provision Improvement Plan (33). Embedding activities within three contrasting case-study sites will allow for identification and analysis of individual and connected challenges that are associated with inequality at a local level alongside the opportunities for cross-sector workforce planning and development and their consequences for families and services. Generalisability of this localised approach to addressing inequity in SLCN and representativeness of findings and the guidance we develop will be assessed through regular engagement with Local Authority Early Years and SEND leads, children's SLT service leads, Family Hubs, and Parent Carer Forums across England via existing regular forums. Synthesis of findings across sites will enable the cross-sectoral, organisational, community and individual level factors that influence successful localised implementation to be identified. Guidance will be developed to enable implementation of the PLACES approach to other localities to support the SEND and Alternative Provision Improvement Plan (33).

5 SETTING - WORKPACKAGES

The study comprises six Work Packages (WP1-6) to address the five objectives (0-5)

WP1. SET UP

AIM: To set up the project, obtain ethics and information governance (IG) approvals

METHODS: Pennington and the Project Manager will develop documentation and materials for ethics and information governance prior to the study commencing, based on PPI already conducted in preparation for the application. We will seek ethics approval from Newcastle University; HRA approval is not required due to the sample population.

Local authorities and NHS services already share summary level data required for WP2 as part of ICB commissioning and evaluation. Data sharing agreements will be put in place to allow sites to share summary level data from WP2 and pseudonymised individual level data for WP5 with Newcastle University. Data sharing agreements will be created to allow Newcastle University to share anonymised individual level data from WP4 with local authorities, and NHS if children become patients of SLT services. University and site IG leads estimate agreements will take three months to execute.

Kent, Oliver, Welsh will recruit local parents to PPI advisory groups at their participating site. Reeves will recruit parents to a national advisory group and provide two 2-hour online training sessions for all parent advisors on the role of research and its life cycle (using PenCRU Family Faculty resources (https://pencru.org) childhood SLCN, SLCN interventions, aims of PPIE and the and the tasks involved. We aim for PPI advisory groups to be inclusive and representative of families at risk of SLCN and will work with the local Parent Carer Forum and family hubs, link workers, local faith groups and third sector organisations supporting families to achieve this. We will provide additional local training via interpreters if necessary. PPI members will be reimbursed for the time taken to train, at INVOVLE rates.

McKean and Pennington will provide half a day online training for local researchers on introducing the parent completed outcome measures to families, conducting the PLS-5 and maintaining data for the study. Local researchers will be SLTs, HVs or EY practitioners who are already skilled in conducting development tests, entering data online, and interacting with parents. Rapley and Robinson will train university-based post-doctoral researchers to gather and analyse data generated in the study. Pennington will confirm membership of the steering group (see Project Management below).

OUTPUTS: 1. IG compliance; 2. Trained PPI groups; 3. Trained researchers; 4. Steering group established

WP2.O1. DEEP DIVE INTO LOCAL NEEDS, PROVISION, AND POSSIBILITIES

AIM: To define children's early language outcomes, local SLCN provision and early years SLCN workforce in each area

PARTICIPANTS: In each area we will work with a local SLCN team comprising parent representatives, service leads and practitioners from NHS, local authority and third sector organisations: children's SLT, Early Years, Family Hubs, Health Visiting and Special Educational Needs and Disability services; Data Managers; ICB children's lead. We aim for at least two parent representatives per area. Parents will be recruited via the local Parent Carer Forum (PCF) and adverts in early years provider premises and social media. PCFs are Department of Education funded fora of parents and carers of children and young people (0-25) with special educational needs and/or disabilities who work with local services to ensure that parent carer voices influence service planning and provision. Given their remit, parent carers involved in PCFs are familiar with working on multidisciplinary strategic projects and require no further training for this work package. We will work with chairs of the PCFs to recruit parents who share characteristics of the families whose children are at highest risk of SLCN in their area as participants in WP2. This approach has worked well in a current study (7).

Parents will be reimbursed at NIHR recommended rates. Team members in each area have agreed to participate if the project is funded (see letters of support).

METHODS: Each participant will be asked to reflect on the services they receive or provide, their accessibility and reach, to help identify groups of children who may not yet accessing interventions and why that may be. Sectors (NHS, LA, third sector) will be asked to prepare summaries of data they currently collect. Data will include:

1. Summary population and community (middle super output (MSOA)) level demographics associated with SLCN will be shared by the local authority

- Income deprivation affecting children index (IDACI)
- Languages spoken, minority ethnic background
- Percentage of eligible 2- and 3-year-old children registered for free education
- Percentage of children completing 2-2.5-year developmental review
- Language outcomes at 2-2.5-year review
- Early Years Foundation Stage Profile outcomes

2. Service level data will include:
    - Descriptions of current universal and targeted SLCN interventions' method of delivery, content, dosage (length and frequency of sessions, duration of programme), population targeted and provider (employer, level of qualification); data on the reach of the interventions (proportion of eligible children receiving intervention) and outcomes (including audit results, parental satisfaction).
    - Descriptions of specialist provision by SLT (pathways); data on waiting lists, referrals by provider, outcomes of referrals (offer vs referral back to universal/targeted service; uptake of offer of intervention).
    - Workforce data will include WTE of practitioners, geographical location, qualifications in NHS, local authority and third sector; number of private, voluntary and independent (PVI) nurseries; number of places in in PVI nurseries.

Data will be shared between participants (and the research team) either using an online repository (e.g., MS Teams, Google drive) or hard copy, at the preference of the local team.

Discussions with service and data managers and ICB leads have confirmed that data required for WP2 are available and can be used in the research with data sharing agreements in place. Local checks show completeness of data is high (≥95%). In one area data show that up take of the 2-2.5-year developmental review is low (70%). Staff wish to examine and address patterns of inequality of access as part of WP2. Data sharing across sectors in this study will support deeper understanding of these under-served groups. Summary level data sharing across sectors is standard practice in multidisciplinary early years' service planning as part commissioning and evaluation by ICBs and previously CCGs. Child and family level data are routinely collected by NHS and Local Authorities and flow to national datasets: NHSE Community Services Data Set (e.g., SLT referral and waiting time data); Office for Health Improvement and Disparities Child Health and Maternal Statistics (e.g. 2-2.5 year review); and the Department for Education National Pupil Database (e.g. Early Years Foundation Stage Profile). Access to the national datasets is not required or desirable for the project as we will develop processes for timely and responsive data use within areas. Local teams will use their own datasets when planning services both in the study and when guidance arising from the study is implemented to enable nimble data-driven quality improvement. The team have experience of using these data in other studies (7).

We will hold one full-day or two half-day face-to-face sessions and up to two 90-minute online workshops with each local team (Participants above) to explore the SLCN of young children living in their local authority using the data they have gathered. Process will be similar to that adopted in JLA priority setting. Each stakeholder group will make brief presentations summarising their locally collected data. Break-out multi-disciplinary groups will identify groups of children most at risk of SLCN who are currently underserved. The local team will rank the order of priority of potential target populations, to finalise the group of children to be targeted in the research. The

same process will be used to identify workforce capacity to provide intervention (e.g., private, voluntary and independent (PVI) nursery staff, childminders, staff in schools with places for 2-year-olds, early years practitioners in family hubs). The research team,
who have used similar methods in previous studies (52, 53) will facilitate the prioritisation, ensuring open debate and transparency. The team also have extensive experience of characterising the distribution and nature of SLCN needs and provision at international, national and local levels to inform the design and implementation of this WP (12, 54).

The researchers will record which data are used in the workshops, who controls the data, how frequently they are collected, the methods used to collect them and their completeness. To meet our aim of identifying cross-sectoral factors that influence successful localised implementation, following completion of all three 'deep dives', the research team will synthesise types of information used to identify underserved groups to create guidance on how to use routine data for SLCN service planning. The guidance will be discussed with the Steering Group and finalised following feedback from HV, SLT and Early Years leads from other areas in engagement workshops (WP5.O5) prior to finalisation.

OUTPUTS: 5. Map of SLCN provision, identification of children at risk including reach, inequalities, needs and the opportunities/ challenges specific to each area. Local results will feed forward into intervention selection (WP3.O2) and evaluation (WP5.O4). 6. Catalogue of types and owners of data needed to support local SLCN planning, for generalisation of the approach (WP6. O5).

WP3.O2. CO-PRODUCTION OF LOCALLY ADAPTED EVIDENCE-BASED EARLY LANGUAGE INTERVENTIONS

AIM: To select an evidence-based intervention and make co-produced adaptations for local delivery

PARTICIPANTS: Local team leads and parent representatives from WP2.O1, plus one EY, one HV, and two SLT practitioners and at least two further parent representatives. Participants will include at least one member of the workforce group identified in WP2 as deliverers of the intervention, plus their service manager (e.g., PVI nursery lead). Practitioner participants will be recruited by their line managers. Parent participants will be recruited through adverts in social media, EY services and the local PCF. The researchers and these practitioners and parents will constitute the Local Adaptation Team.

METHODS: WP3 is underpinned by co-production principles of equality, diversity, accessibility, and reciprocity, valuing the unique contribution of each stakeholder. Materials will be individualised according to each group's needs (e.g., translated, provided in Easy Read format). Methods also draw on ADAPT guidance (55) which includes the following steps which will be completed as part of this WP: 1) forming an adaptation team; 2) considering intervention-context fit and choosing an intervention 3) planning and undertaking adaptation.

INTERVENTION SELECTION: In a short-day face-to-face meeting arranged around nursery / school timetables, the local team will summarise the results of WP2, describing local need and rationale for the target group for new members. The research team will present a menu of the evidence-based interventions described in the evidence review above that are suitable for children of the targeted age range. Evidence on each intervention will include the age of children targeted; dosage (number and duration of sessions, duration of intervention); contents; personnel delivering; individual or group delivery; materials required. The researchers, drawing on experiences of intervention co-design ((10, 56) will facilitate open, transparent, and inclusive discussion of the interventions and their suitability for the target group of children identified in WP2 and the local context (10). Activities such as ranking, and SWOT analysis will be used to help teams to their select an early language intervention from the menu.

LOCAL ENGAGEMENT: Kent, Oliver and Welsh will work with local service leads from WP2 to engage and recruit providers, using local networks and opinion leaders; a strategy which has been successful in our previous work (10, 57, 58). We will engage with parents of young children with SLCN in face-to-face meetings and local social media about intervention selection and localisation to encourage them to contribute

INTERVENTION ADAPTATION: The Local Adaptation Team and the researchers will tailor the selected programme for local implementation (e.g., adaptation of materials such as creating online asynchronous training materials, culturally adapting parent guidance leaflets, preparing lesson-plans, or creating book- reading guidance aligned with current curricula). Local adaptations will specify who will deliver the intervention, where, how often, for how long (minutes per session), over what duration and the nature of the training model offered to those who will deliver the intervention. Potential implementation barriers and solutions explored could include high staff turn-over requiring development of flexible online training; competing priorities in nurseries requiring training for school senior leadership teams; and pressures of large class-sizes tackled through involvement of parent/caregiver volunteers. Any such adaptations would be created through stakeholder co-design. The adaptation will commence in the second part of the face- to-face meeting in which the intervention is selected and continue in up to two further two-hour online meetings with a smaller group of participants (one EY, HV and two SLT practitioners and two parent representatives). The local researchers will draft intervention manuals and compile materials with CM and LP between co-production meetings. Our current and previous research has shown this process to work well (7, 10, 53, 56, 58). We will use the TIDieR framework (46) to specify the intervention and the INCLUDE Ethnicity and Socioeconomic Disadvantage frameworks to help define the tasks required to ensure inclusion of local populations (https://www.trialforge.org/trial-forge-centre/diversity/).

TRAINING: McKean and Pennington will train the local researchers to train local personnel to deliver the intervention, in a train-the-trainer model, which aims to encourage sustainability. Training will take up to a day and will be delivered face to face. The local researcher will be supported to develop the materials needed to train local personnel and for local personnel to deliver the intervention. Materials will be translated, and Easy Read versions produced where necessary. The research team will develop fidelity checklists for each intervention and pilot these with three providers before they start to implement the intervention. CM and LP draw on extensive experience of intervention development and evaluation research including development of manuals, training, fidelity and dosage monitoring tools (6, 10, 56, 58, 59).

OUPUTS: 7. Programme specification for each local adapted intervention using TIDieR framework. 8. Materials produced for training and delivery for each local adaptation of an intervention. 9. Staff skilled in intervention delivery

WP4.O3. IMPLEMENTATION OF LOCALLY ADAPTED EVIDENCE-BASED EARLY LANGUAGE INTERVENTIONS

AIM: To implement and embed accessible locally adapted evidence based SLCN interventions in each participating site.

PARTICIPANTS: Local early years providers; children with/at risk of SLCN aged 0-3yrs and their parents (n=120 children recruited per area).

SAMPLING: Detailed inclusion criteria will vary depending on which groups local areas choose to target. Inclusion could therefore be determined by geographical area, early years provision, child level risks, social disadvantage etc. No exclusions will be made based on the presence of other developmental difficulties; children with SLCN as part of multiple long-term condition (e.g., cerebral palsy, autism spectrum disorder, Down Syndrome) or languages spoken. We estimate that around 15% of families in the total sample will have English as an additional language (EAL). Current data from SLT caseloads show that 40% of children have English as an additional language in Wolverhampton, 3% in North Tyneside, 3% Redcar and Cleveland). Sites have 602-1414 two-year-old children eligible for free childcare due to income and/or SEND. Exclusion criteria: children receiving SLT from either NHS or independent practitioner.

METHODS: Local providers deliver the intervention for 3 months to each child. They will have two online review and trouble-shooting meetings with local researchers to problem solve barriers and share enablers of good practice across practitioners implementing the interventions. Providers will be encouraged to share learning and experiences of delivery in their current networks. Assessment of fidelity of delivery will be completed through local researcher log of training delivery and attendance, local practitioner completion of a delivery log (including date of sessions; children attending), record of attendance for targeted children and observation of one intervention delivery session by the local researcher using the fidelity checklists developed in WP3.Completion of the fidelity checklist will be followed by supported reflection and forward planning. Local researcher field notes, logs and the fidelity checklist after each of these contacts will enable qualitative and quantitative evaluation of treatment fidelity.

FEASIBILITY OF RECRUITMENT: Delivery settings and children will be recruited to the study soon as the target group and the provider workforce is identified in WP2. In each area large numbers of children are at risk of SLCN (see Design). Two areas have provisionally identified nurseries as a setting for intervention delivery, estimating recruitment of 10-12 children per nursery. A call for Early Years Settings to participate in a recent intervention study yielded more settings than could be accommodated; staff in those settings supported recruitment, 80% of 80% of children approached were recruited within 2-3 months (58). Where the chosen target group has less well developed relationships with services we will consult with local teams and PPI groups to identify and address barriers to inclusion using the NIHR INCLUDE frameworks (https://www.trialforge.org/trial-forge-centre/diversity/).

Intervention provision for children whose home language is not English will follow Royal College of Speech and Language Therapists' guidance which specifies delivery of intervention in that home language through the use of interpreters and other trained practitioners around the child (e.g., Early Years Practitioners) who are proficient in that home language (60). Intervention delivery in home languages other than English will be considered at the adaptation stage (WP3) including questionnaires to understand children's profile of language exposure to determine the most appropriate language for intervention (61). Interpreter services available at local sites will be utilised as appropriate.

Embedding interventions: We will make use of local team meetings and networks to foster implementation, e.g., action learning sets are currently used on one area. Local researchers will encourage and support teams to use these for reflection and problem-solving for implementation.

Reach: Demographic data on age, sex, gender, ethnicity, and languages spoken in the home will be collected to ensure the participants (parents/caregivers, and children) included in our study represent the diversity of families recognised to be at higher risk of SLCN.

Given that this study aims to target under-served groups or settings, strategies to maximise retention and allow for attrition have been considered carefully. Retention will be maximised through strategies developed through the PPI work described above. These will include Easy Read, translated and video versions of information sheets, and direct contact by trusted practitioners. In addition, the co-design and adaptation work in WP3 explicitly aims to address feasibility and acceptability barriers of the intervention itself to target groups. Published estimates of drop-out rates for parenting interventions range from 28- 50% (62). Local data from sites in the study suggest that interventions delivered at home have a drop-out rate of around 50%. However, drop-out for interventions in early years settings are lower and are mostly dependent on the level of mobility of a given population, with recent SLCN effectiveness trial reporting a 9% drop-out (63). To compensate for drop-out and the inclusion of children who have English as an additional language and children with multiple conditions, for whom we cannot calculate standard scores (see WP5) we will over-sample, recruiting 25% more children than is required by power calculations.

OUPUTS: 10. Embedded interventions for sustained service organisation and delivery. 11. Logs of intervention fidelity.

WP5.O4. EVALUATION OF LOCALLY ADAPTED EVIDENCE-BASED EARLY LANGUAGE INTERVENTIONS

AIM: To evaluate the reach, effects, costs, return on investment and implementation of the locally adapted interventions to providers and families

Intervention Effects

Primary Outcome: Child language

PARTICIPANTS: Children with SLCN who were offered intervention in WP4.

METHODS: Child language will be measured using the Preschool Language Scale 5th UK Edition (PLS- 5) (64), a validated, standardised test of spoken language comprehension and expression.

Measurements will be taken 6 months before baseline ("pre-baseline"), at baseline, and 6 months post baseline (that is 3 months following the end of the intervention). For monolingual English-speaking children without multiple long-term conditions, we will employ children's language PLS-5 standardized score (a score of 100 represents the performance of the typical student of a given age). For children whose home language is not English there are limited valid standardised tests available. RCSLT guidance recommends assessment in a child's home language (60). Adaptation of English Language tests to other languages can, if conducted with care, yield useful clinical data (60). However, scores from such adaptations cannot be used to generate standard scores nor can such scores be generated for tests conducted in English for bilingual children. In order to enable the inclusion of children who are bilingual or whose home language is not English, we also consider PLS-5 growth scale scores which are not age-standardized, hence allowing the estimation of language ability and change over time independent of a child's peer group. For monolingual children (Sample 1) we will assess whether:

1. Children's mean PLS-5 standard score, when adjusted for the observed change in standard score in the pre-baseline period, has significantly changed in the post-baseline period.

2. Children's mean PLS-5 standard score, as compared to baseline, has significantly changed in the post- baseline period.

For all participants - monolingual English, monolingual non-English and bi/multilingual (Sample 2) we will assess:

3. Children's mean PLS-5 growth scale score, when adjusted for the observed change in growth scale score in the pre-baseline period, has significantly changed in the post-baseline period.

4. Children's mean PLS-5 growth scale score, as compared to baseline, has significantly changed in the post-baseline period.

The sample size calculation which we have carried out is based on a difference-in-difference view of the problem as described above for Question 1. The task is to demonstrate that the differences between post- baseline and baseline estimates are significantly different to the ones between pre-baseline and baseline estimates. This becomes then a paired t-test problem based on these sets of differences. For the post- baseline period, we anticipated an effect size of 0.4, based on results by Law and Charlton (39). For the pre-baseline period, an effect size of 0.1 is deemed appropriate, allowing for some spontaneous improvement/regression to the mean may occur, yielding a net effect of 0.3 to be detected. A sample size of 90 is obtained using the "expected effect size" of 0.3 in https://statulator.com/SampleSize/ss2PM.html (no other quantities were specified, apart from 80% power and 5% significance level). The result was independently verified using the Sample size calculator for "Before-and-after-studies" at https://sample- size.net/sample-size-study-paired-t-test/. Explicit sample size calculations for the longitudinal models we propose require the specification of parameters of which we do not have good estimates. We checked, by mathematical proof, that the intervention effect from the longitudinal model, in the proposed discrete-time parametrisation with three measurement points, corresponds to a difference-in-difference estimator so these approaches are essentially equivalent and hence the sample size calculation applicable. Therefore, any sample size deemed sufficient for the difference-in-difference approach will also be appropriate under longitudinal modelling, for the specific inferential question of interest. This will be inflated to 120 to allow a 15% loss to Sample 1 due to the necessary exclusion of children with EAL in the most robust approaches to analyses (Q1-2), and a further 10% loss to follow up.

The analysis will use paired t-tests (Questions 2,4) and longitudinal modelling (Questions 1,3). Longitudinal models will include a child-level random effect and a factor-coded time variable to identify the effects of interest. The adjustment for pre-baseline trajectories facilitated by these models accounts for regression- to-the-mean effects (since the typical magnitude of the regression to the mean is subtracted from the overall effect). The three repeated measures in the longitudinal models (at pre-baseline; baseline; post- baseline) are sufficient for us to conduct robust analyses to test our hypotheses. We will carry out a difference-in-difference analysis (difference post-baseline to baseline vs difference baseline to pre- baseline) and fit longitudinal models which yield parametric estimates of the difference-in-difference effect. From an analytic point of view, a model-based, longitudinal approach (as opposed to a "plain" difference- in-difference analysis) has several advantages. Longitudinal models are robust to missing (outcome) data; that is if for a particular child one or more measurements are missing, all the remaining measurements can still be used in the model and will contribute to the explanatory power of the model (88). They allow for a decomposition of variance between and within children, enabling additional insights into the source of variation within and between children's trajectories. This will allow us to understand and characterise unpredictable communication changes. They also allow for the inclusion of covariates. The covariates will include including indicators of socioeconomic status, ethnicity, language spoken, and potential confounding variables such as the arrival of siblings, parental return to work, changes in childcare etc. Although the study is not powered to detect significant effects of these covariates (even though this may well occur); the purpose of these covariates is to investigate whether adjusting for potential confounding by such variables has any implications for the intervention effect, in the sense of a sensitivity analysis. Covariates that do explain any variation of the outcome measure will increase power (and so reduce the required sample size) hence ensuring that our methods continue adequately powered under inclusion of covariates (https://educationendowmentfoundation.org.uk/projects-and-evaluation/evaluation/evaluation- guidance-and-resources/evaluation-design). Logistic regression models will be used to detect change in the proportion of children accessing services within areas. Due to the expected strong heterogeneities between areas, the primary analysis will consider each area separately, i.e., the data will not be pooled for analysis. However, as a sensitivity analysis, a random effect meta-analysis on the pooled data, with random intercepts for each area, will be considered.

Secondary Outcomes

1. Child quality of life; parent mental wellbeing

PARTICIPANTS: Children with SLCN who were offered intervention in WP4 and their parents.

METHODS: Secondary outcomes are children's quality of life, measured using the Pediatric Quality of Life Inventory (PedsQL) (65), and parents' wellbeing, measured using the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) (66), both well validated instruments.

Measurements will be taken 6 months before baseline ("pre-baseline"), at baseline, and 6 months post baseline (that is 3 months following the end of the intervention). The secondary outcome analysis of PedsQL and WEMBWS will follow similar lines as the primary outcome analysis (in particular, it will also adjust for pre-baseline trajectories).

2. **Child language and communication**

PARTICIPANTS: Children with SLCN who were offered intervention in WP4; children who were not offered intervention in WP4 matched on IDACI decile; children who were not offered intervention in WP4 matched on LSOA.

METHODS: The secondary outcome for the evaluation of intervention effects is child language and communication, as routinely measured using the six language development items on the Ages and Stages Questionnaire (ASQ), which forms part of the national 2-2.5-year developmental check by health visitors. Scores on the ASQ are categorical: Typical, Borderline, At Risk. Local authority partner sites have confirmed that local data collection currently includes number of children in the cohort; ASQ completed; categorical score showing where appropriate progress is not reached (specific domain identified, i.e., communication etc); what intervention is offered and what the outcome for the child is, including referrals to specialist Speech and Language services.

Data on onward referral will enable us to count the numbers of children in each category in the group that receive the intervention in our study and in a matched group of those that do not. We propose to compare ASQ language outcomes for children receiving the intervention with 1) children from matched IDACI deciles who did not receive the intervention, assessed over the same time period; 2) children from the same LSOA in preceding pre-COVID years. Locality partners report data are available from 2016.

Due to the categorical nature of the ASQ scores, the comparisons of children receiving the intervention with groups 1) or 2) will be carried out using Fisher's exact test for contingency tables (which avoids the need for collapsing categories in the presence of small counts). No regression analysis will be carried out for this outcome. The comparisons will be interpreted cautiously; in part due to the inherent difficulties in matching highly diverse communities but also due to the lack of sensitivity of the ASQ to detect change. This is because the ASQ yields a categorical rather than continuous outcome and due to the timing of measurement which will likely be part way through the intervention process for most children rather than after its completion.

Health Economic Evaluation

The economic component will estimate the costs and consequences associated with the locally adapted interventions and will consist of four interrelated components: 1) A Micro-Costing Exercise; 2) Cost Consequence Analysis; 3) Contingent Valuation Study; 4) Social Return on Investment Study.

MICRO-COSTING: All costs associated with the delivery of the different interventions (as well as current practice) will be collected as part of a micro-costing exercise. This will include set up costs, equipment costs, training, operational costs and associated staff costs. Data to inform this costing will be gathered from discussions with the SLCN teams in each local area as part of WP2, WP3 and WP4. The perspective of the analysis (i.e., whose costs and benefits are considered) will be the NHS and personal social services, but we will also take a wider perspective by including costs borne by families, for example out of pocket expenses on health care and the time and travel costs of accessing care. Health care resource use of the child will be collected via a parental completed Health Care Utilisation Questionnaire completed at 6 months prior to the intervention (“pre-baseline”), baseline, and 6 months post baseline (3 months following the end of the intervention period). This questionnaire will be based on questionnaires previously developed by the Health Economics Group at Newcastle and the Database of Instruments for Resource Use Management (DIRUM) website (www.dirum.org) and co-designed with clinical experts and the project PPI advisory groups in order to identify relevant areas of resource use to be collected in addition to the standard resources used in primary and secondary care. Other costs such as parent time off work/out of pocket payments will be collected through a one-off time and travel questionnaire completed at the 6- month post baseline data collection point. The responses to these questionnaires will be complemented with information from appropriate costing resources (for example the Unit Costs of Health and Social Care) (67) in order to determine the total per participant costs of the different interventions. The use of these costing methods draws on Ternent and Robinson’s previous experience of large NIHR funded studies (8, 68).

COST-CONSEQUENCE ANALYSIS: NICE guidance (69) recognises that complex interventions such as locally adapted early language interventions are likely to have a number of different costs and outcomes, over several sectors and recommends that a broad, societal perspective be considered. Therefore, we propose implementing a Cost Consequence Analysis (CCA), where disaggregated costs and a range of outcomes are presented to allow readers to form their own opinion on relevance and relative importance to their decision-making context (70). A wide range of outcome measures will be considered in the CCA, including disaggregated costs, the number of children referred to SLT, child language development outcomes (PLS-5), parent well-being and perceptions of care (WEMBS) and child health related quality of life (proxy-reported PedsQL). Although the PedsQL is widely used among paediatric patient populations, it is currently not possible to estimate Quality Adjusted Life Years (QALYs) from the measure. Therefore, we will indirectly calculate QALYs using a previously generated mapping algorithm to the CHU-9D (71) and include this in the CCA as alternative way of measuring the benefit of the intervention. Indirectly calculating QALYs in this manner has its limitations, however there is currently no validated generic HRQoL measure appropriate for the paediatric patient population. The use of these methods draws on Robinson’s growing interest in the measurement and valuation of HRQoL in children (72). In order to assess whether both the costs and effects have significantly changed in the post-baseline period, the incremental costs and incremental effects will be estimated using identical methods as the statistical analysis of the main outcome measures, specifically appropriate longitudinal models which include child- level random effects and a time variable to identify the parameter of interest. To account for unobserved individual characteristics that could affect both costs and effects and potentially lead to correlation between these two variables, these models will be estimated in a seemingly unrelated regression framework (73).

CONTINGENT VALUATION STUDY: Alongside the CCA, we will also implement a parent completed contingent valuation (CV) study as an alternative method of valuing the intervention. CV is a stated preference method used to attribute monetary values to health care services, in which responders are asked to estimate their willingness to pay (WTP) for a health care service. An online survey, developed by the project team and with input from the PPI advisory groups, will be used to capture this information. The exact question that will be asked in the WTP survey will be determined in the study period through consultation with the wider study team, PPI groups and relevant stakeholders. The WTP survey will be completed by a sample of parents of those taking part in the intervention at the 6-month post baseline data collection point, with the results being presented as part of the CCA. Hard copies of the survey will be made available to parents who prefer paper questionnaires. A formal sample size calculation for the CV study is not possible, and a recent review of CV studies in health found sample sizes which ranged from 40 participants to over 1,000 (74). Assuming a sample size of 120 for each site we will aim for an 80% completion rate, which would provide a sample size of 100 participants per site and 300 overall. The use of CV methods draws on Ternent's previous experience in this area.

SOCIAL RETURN ON INVESTMENT: we propose combining the data being collected as part of WP5, the contingent valuation study and data sourced from the literature to estimate the monetary return of the locally adapted evidence-based early language interventions in the short and medium term through a SROI analysis. The SROI provides a framework for the consistent and reproducible identification, measurement and valuation of impacts that might occur in the short and medium term. The CV approach provides a mechanism to value impacts and outcomes that are identified.

The return will be calculated as the return of the post-intervention period (intervention) to the pre- intervention period (control) with the time horizon being school leaving age (18 years of age).

A SROI evaluation has five stages: 1) Establishing scope and identifying stakeholders; 2) Mapping outcomes; 3) Evidencing outcomes and giving them value; 4) Establishing impact; 5) Calculating SROI ratio.

Stage 1 and Stage 2 will be integrated into WP2. Discussions with some of the stakeholders involved in WP2 (parent representatives, service leads, practitioners from NHS, local authority and third sector organisations) will help to shape a map of the potential impacts and outcomes (both positive and negative) for the intervention and a detailed impact map will be developed.

Stage 3, Stage 4 and Stage 5 will be integrated into WP5. To evidence outcomes and give them value relevant indicators for each outcome will be collected as part of the resource use questionnaire and supplemented with others sourced from the existing literature. Appropriate monetary values for each indicator with be gathered from market prices and previously developed bank and social values where relevant. To establish the impact of the intervention the financial proxy value for each indicator will be applied to the magnitude of each outcome indicator. To calculate the SROI ratio we will divide the estimated net present value of impact by the estimated net present value of the investment. A ratio value greater than one indicates an activity that is socially beneficial for the given level of investment.

Qualitative Exploration

This qualitative process evaluation will draw on focus groups with early years professionals at sites, interviews with parents and professionals, as well as observations of intervention development and delivery. It will explore the processes of sharing data on children with SLCN; identifying and targeting of under-served groups; selection, development, introduction, embedding and sustaining of the implementation of the tailored interventions.

PARTICIPANTS: We propose to recruit around 30 local early years professionals working across the three sites and around 23 parents/guardians of children at risk of SLCN to take part in focus groups and/or interviews, with additional local early years professionals recruited to observational work. We anticipate that 5-6 will have English as additional language; we will use interpreters to allow parent carers to participate fully in the evaluation. Numbers included are to give an indication of the amount of data to be collected, and to enable the study to be appropriately costed. Our sampling strategy is informed by our current and prior experience (9), our theoretical framework (75) and what we already know about the study context. In keeping with the principles of rigorous qualitative research, we will be responsive to the study, and note that in some cases fewer interviews or focus groups may be conducted with some, and additional data may be collected in response to our emerging analysis and/or study events. If saturation – notably both theoretical saturation and inductive thematic saturation (76) is not achieved in an area, we will be responsive and we will theoretically sample participants and/or events to further develop and refine conceptual ideas.

METHOD: We will undertake focus groups (n=3 per site; n=9 focus groups in total) with local early years professionals at each site (n=6-10 staff per site) who are involved in the deep dive into local data, and/or the selection, development, training or delivery of the intervention. We will focus on implementation processes (e.g., interest, engagement and workability; inter/intra-professional and organisational working, trust and delegation; integration into broader early years agendas and landscapes) and the practical delivery of tailored evidence-based early language intervention (e.g., training, resources, impact on day to day work, feedback from children and parents, sustainability). We will undertake them at three separate time points, months 8, 16 and 24 to explore the changes over time. Focus groups will last around 60 minutes.

We will also conduct follow-up qualitative interviews (n=3-4 per site; n=9-12 interviews in total) with those staff involved with training or delivering the interventions to further explore emerging and additional issues. Formal interviews will last between 40-60 minutes and may include one or two interviewees. Additionally, those delivering the intervention will be asked in the action learning groups they attend to keep document their experience of providing the service and identify any training needs, areas for further learning, or additional support. We will also conduct regular rapid debriefs with trainers during training periods.

We will conduct observations at each site (n=5-7 per site; n=15-21 visits in total), to explore delivery and management of the process, including shadowing key professionals**.** This may include observing intervention development workshops, team meetings, training events or the delivery of the early language interventions. We will take fieldnotes only.

Finally, we will conduct interviews (n=7-8 per site; n=21-24 interviews in total) with parents/guardians of those children receiving the interventions. These will explore their perceptions about the evidence-based interventions (e.g., initial information provision/engagement, acceptability, hopes, ideas and/or concerns on impact on child and family). Some parents/guardians (n=3-5 per site; n=9-15 interviews in total) will be approached for a follow-up interview, in order to understand their experiences over time. Formal interviews will last between 30-60 minutes - follow-up interviews often take up less time - and may include the one or two parents/guardians.

Informed consent procedures will ensure that participants understand that participation is entirely voluntary and that they can withdraw from the focus groups, interviews or observation at any time. Focus groups and observational work will generally be undertaken face-to-face; interviews will mostly be undertaken remotely (telephone or online). Where necessary, we will draw on local professional interpreter services, to support the parental/guardian interviews. We know from our prior experience that parents (e.g. (9)) - as well as staff (e.g. (8)) - routinely prefer online/telephone interviews as they can more easily integrate them into their (often rapidly changing) schedules. We will arrange interviews at a time and, in relation to face-to-face interviews, place that suits participants.

Data analysis will be on-going and iterative throughout the study. Interviews and focus groups will, with consent, be audio-recorded, transcribed verbatim and edited to ensure anonymity of respondent. Interpreters will be used to ensure inclusion of parents who speak languages other than English. Recordings of interviews made via interpreters will be professionally translated, using an agency local to the interview site. Contemporaneous field notes from non-participant observation will be edited to ensure anonymity of participants. The analysis will be theoretically informed by relevant implementation frameworks and theories (e.g., Normalization Process Theory (75); Expert Recommendations for Implementing Change (77); Theoretical Framework of Acceptability (78)) and related areas (e.g., organizational studies and sociology of professions (79)). It will be conducted according to the standard procedures of rigorous qualitative analysis (80) including open and focused coding, constant comparison, memoing (81), deviant case analysis (82) and mapping (83). We will undertake independent coding and cross checking. Data will be analysed collectively in weekly ‘data workshops’ where the qualitative research team share and exchange interpretations of key issues emerging from the data, as well as bi-monthly data workshops with the broader research team, with additional data workshops with local and national PPI groups. We have experience of recruiting similar participants, in similar numbers and time frames from other studies and in applying the methods here (7, 9).

Multiple long-term conditions, studies within a project (SWAP)

A SWAP will evaluate the acceptability and feasibility of the implemented intervention to children who have SLCN as one of multiple needs associated with long-term Neurodisability conditions such as cerebral palsy and Down Syndrome. Children with multiple long-term conditions will be recruited to WP4 and receive intervention. Some children with these more complex needs will already be receiving services, such as physiotherapy and occupational therapy, but many will be waiting for speech and language therapy and/or to enter autism diagnostic pathway, due to long waiting lists (33). Local researchers will identify children with multiple long-term conditions in the data collection process. Data from these children will be excluded from the analysis of the Intervention Effects on the primary and secondary outcomes and the economic analyses, as their language development trajectories health and care needs may be very different to those of children without complex Neurodisability. They will be included in the SWAP. We will sample 10-12 children to maximise diversity in conditions (including development domain affected, language spoken in the home, age and IDACI). We will interview their parents during and following the intervention. We will aim for at least two of these parent carers to have English as an additional language. We will also interview the practitioners who provided the children’s intervention. Interviews will examine the acceptability and perceived effects of a targeted (rather than specialist) early language and communication intervention for children with multiple conditions, the potential impact on the timing of and confidence in referral to specialist pathways, and the confidence of local practitioners in supporting families of children with complex needs. We used similar methods with parents of children with Neurodisability in previous projects (7, 84, 85)

Synthesis

We will combine the findings of the three evaluative components above to understand the extent to which locally adapted and embedded interventions bring benefits to children, families and services. We will utilise systems thinking theory and tools to visualise and describe a) the final models of the interventions implemented and b) the process of creating the necessary change across the system for their implementation (86, 87). The intervention model (a) will capture the complex and interacting effects of the intervention across the system including effects on children, families, settings, costs, patient flow and services. This will be achieved using tools such as causal loop and stock and flow diagrams, and narrative interpretation (87). We will draw on implementation theories and use tools such as contextual maps to develop the process model (b) that will capture implementation over time at multiple contextual levels (services, settings, professionals, families, children), the interactions between those levels, and the barriers, enablers to implementation. Through this synthesis we will identify the cross-sectoral, organisational, community and individual level factors which influence successful implementation and map their benefits and consequences across the system.

OUTPUTS: 12. Estimation of the effects of localised SLCN interventions on children's early language development. 13. Estimation of the reach of localised interventions and their impact on SLT caseloads.14. Costs of delivering the interventions 15. Cost effectiveness of the interventions 16. Willingness to pay for the interventions 17. Identification of the factors affecting the local implementation and embedding of adapted interventions. 18. Indicators of the acceptability of generic localised interventions for children with multiple long-term conditions. 19 Visual and narrative models of whole systems interventions and implementation processes.

WP6.O5. OUTPUTS, ENGAGEMENT, DISSEMINATION AND IMPACT

Outputs

GUIDANCE. We will create written guidance for local authorities, NHS trusts, ICBs, and third sector providers on how to implement the process investigated in the research to extend the reach of SLCN support for preschool children. Guidance will focus on methods to transfer learning to other contexts and will comprise:

- A framework of data sources and the information required to map SLCN provision and outcomes, identify inequalities, local needs, and opportunities.
- How to adapt evidence based SLCN intervention to meet local needs.
- How to specify interventions for local delivery.
- How to promote the embedding of locally adapted SLCN interventions for sustainable delivery.
- How to evaluate intervention reach and success.

Guidance will be made available on the study website and disseminated to service providers and commissioners and policy makers.

POLICY BRIEFS: We will create briefing papers for local policy makers (local authority SEND and Early Years Leads, Designated Clinical Officers and commissioners) and national policy leads (NHSE/I Learning Disability and Complex Needs leads; Association of Directors of Children's Services). We are closely linked with CDC sharing events and forums and will take up opportunities to share at CDC National Events attended by health and SEND commissioners. We will also submit the briefing papers to the Chair for the All-Party Parliamentary Group (APPG) on Speech & Language Difficulties and present the findings at an APPG meeting. We will offer to present at Public Policy Exchange events.

ACADEMIC PUBLICATIONS AND PRESENTATIONS: In addition to our report to NIHR, we will prepare at least four open access articles for major child development and child language journals – Early Childhood Research Quarterly (Economic Evaluation); Journal of Child Psychology and Psychiatry (child outcomes); the International Journal of Language and Communication Disorders (Frameworks for implementation); Child: Care, Health and Development (SWAP). We will present the findings at the RCSLT and National Centre for Family Hubs annual meetings, which focus on child language intervention integrated services for early intervention respectively. If possible and at no cost to NIHR, we will present data at the International Conference for Integrated Care and the International Association for the Study of Child Language.

Engagement and Dissemination *informing study participants, parents, practitioners and policy makers*

We will create a project website, where we will post information about the study, its aims, design and current status. The website will be written in plain English for maximum accessibility. We will also post short videos describing the study, interim and full findings to the website. We will use our existing, and where necessary create study specific, Facebook, Twitter and TikTok social media accounts for the study to engage with parent carers, young people, and practitioners.

Throughout the project we will keep participant parents and practitioners in the study sites informed of our progress through summaries for local newsletters, notices to be posted in local services e.g., Family Hubs, and social media accounts. Local PPI groups will inform local dissemination strategies.

Reeves, supported by Pennington, McKean, and the PPI advisory groups, will create plain language summaries, and share these with families via our social media and Speech and Language UK and other support organisations, such as Afasic and the National Autistic Society. We will present results in webinars for parent carers, hosted by Speech and Language UK.

We will host online meetings and webinars to present and discuss the drafts of the guidance we generate with practitioners and service leads from across the UK to ensure generalisability of the guidance. The events will be supported and advertised by Speech and Language UK, the Institute of Health Visiting and the Royal College of Speech and Language Therapists.

We will also present interim findings at regular meetings of current networks, such as the regional SLT Managers' networks, HV and Children's SLT service lead professional networks. We will produce written summaries of interim and full results for practitioners and make them available via the RCSLT and iHV websites, professional magazines, such as the Bulletin (direct mailed to 20,000+ RCSLT members), presentation(s) at relevant clinical excellence networks e.g., Promoting Communication in the Early Years RCSLT CEN. We will also disseminate the findings to SLTs and HVs internationally, via our membership of the International Association of Communication Sciences and Disorders (IALP) and our links to the European Speech & Language Therapy Association (ESLA).

Impact: *Ensuring outputs enter health and care services or society as whole; longer term impact* Increases in language and communication skill could have far-reaching impact, allowing not only better interactions, relationships, and access to education in childhood, but also potentially helping to prevent adverse outcomes, such as contact with the justice system where 60% of adults struggle with communication (20-25).

We anticipate that the guidance developed will embedded through local pathways within the three sites. We will create policy guidance that can be adopted across the UK to address how can we identify inequities in SLCN support and implement localised interventions to support the communication development of children who are underserved by current provision. This will include guidance on how multisector services can work together with parents to identify children most at risk of SLCN, adapt interventions to meet local needs and deliver them in a way that is accessible and inclusive, to increase equity of support and widen participation. The guidance will enable a planning, implementation and evaluation cycle that should increase child language and communication development, child quality of life and parent parents' wellbeing. Regions and localities will be able to use and reuse the guidance to plan prospectively to meet the changing needs of their populations, now in the aftermath of COVID-19 and going forward longer term, to drive increases in children's language and communication and parents' satisfaction with services. We will capture downloads of the guidance and the URL location to track reach and impact potential.

Throughout the project we will meet regularly with NHSE Leads for Children's Allied Health and Community Services who are leading the SLCN programme ELSEC in the SEND and Alternative Provision Improvement Plan. We will share intelligence arising from the complementary projects, so that learning has maximum impact. We will refer to the ELSEC progress and findings in our dissemination, so that findings from the two projects are shared in tandem. Guidance (see Outputs above) will be developed in conjunction with NHSE ELSEC leads, other members of the steering committee who are service leads and policy advisors, and PPI advisors. In addition to shaping the guidance, the steering group will support us in targeted dissemination to senior leaders, managers, and practitioners from across education, health and social care to ensure that the findings are fed into system planning for service development. Our international advisors will support dissemination outside of England through their international policy, and practice networks and knowledge of relevant dissemination platforms. Following completion of the study and we will continue to work with key charities who lobby for improvements to support for those with SLCN and SEND so that they can continue to feed in the lessons from the research when opportunities for policy change arise, so that the impact of the findings stay live.

What further funding or support will be required if this research is successful?

In the future, we will seek further support from NIHR to study long-term outcomes of participant children. We will seek consent for this follow up at the point of participant recruitment and apply for funding for this in a future application. Funding would be used to collect more detailed long-term outcome data, such as children’s language outcomes, including referral to SLT, and educational attainment during primary school.

Barriers to research adoption and implementation

A key output of this research will be guidance for other localities to implement similar processes to support children’s speech, language, and communication skills in their area. The difficulties translating the research finding into practice will be mitigated to some degree by the research design, which is rooted in daily practice and specifically focused on implementation. However, difficulties may arise if comparable resources are not allocated to other services attempting to implement the guidance e.g., local communication champions. We will work closely with key national stakeholders, namely NHSE, DHSC and DfE, to highlight this risk. Successful dissemination of the findings/guidance to local services will also be imperative. To achieve this, we will utilise our national communication channels, to SLTs and HVs, alongside a range of other targeted outputs (see Dissemination).

A further potential barrier to adoption and implementation arises from the fact that our project will develop solutions tailored to specific local requirements. Hence, it will not be optimal to simply copy the same approach in other localities. We will ensure this requirement is clear in the guidance produced, including evidence-based suggestions for understanding your local population and adapting the approach to meet their specific needs.

6 ETHICAL AND REGULATORY COMPLIANCE

Ethical Approval

Prior to the start of the study, approvals will be gained from Newcastle University Ethics Committee for all aspects of the study. HRA approval will not be sought due the participants not being NHS patients or service users. We will collect the minimal amount of patient data for the study and all data will be treated confidentially, following the Data Protection Act 2018 and GDPR.

All participant facing documents will be version controlled and reviewed by the PPI advisory group and Study Steering Committee prior to the study commencing. Any amendment to documents will be clearly documented by the project management team and a record retained.

The Chief Investigators and an experienced project manager will lead the application for ethics, and all approvals. All have appointments with the lead academic institution and will have sufficient time to prepare and submit documentation and respond to queries. Newcastle University will act as research sponsor for the study.

For this study we are not proposing to establish a Data Monitoring and Ethics Committee. Instead, the steering committee with representation from the Sponsor will have complete oversight to ensure the ethical conduct and safety of participants within the study. The group will seek advice and input from those with relevant expertise for all aspects governing the conduct and management of the study.

Assessment and management of risk

AData Management Plan and Data Protection Impact Assessment will be in situ for the duration of the study and analyses

Patient & Public Involvement

Four parent advisory groups (one national and one per site, 6-8 parents per group) will advise on study conduct and dissemination. PPI advisors will be selected to represent the families targeted in the study. Reeves (Co-I, PPI Lead) will be the primary contact for the National Parent Advisory Group; Kent, Oliver and Welsh will lead the parent advisory group at their site. It is likely that parent advisors will change during the lifecycle of the research, given the demands on families of very young children and the likelihood that parents may have further children. This approach has worked well in our research; members of the groups have contributed in different ways and at different time points (7, 53).

We will recruit parents from the local sites, using local networks, and from across the UK via Speech and Language UK. We will seek advisors who have preschool or primary school children with SLCN. Local advisors will reside within the participating authority. No other inclusion criteria will be applied, and we will aim to recruit a diverse group. We will advertise the opportunity using active community groups in local areas. We will provide interpreters where needed. Local parent advisors will not be excluded from joining the study as participants if their children are within the group targeted by local teams in Work Package 2.

Reeves, Head of Evaluation at the families support organisation Speech and Language UK, will lead the involvement of parents in local and national Parent Advisory Groups. The groups will advise on the methods of dissemination to parents in the participating sites and across the UK; the form and content of documentation for the project (e.g., information sheets and consent forms); the content and design of the study website; the analysis of the findings and their dissemination (see Project Timetable). We will consult with Parent Advisory Groups at the start of each work package and as we begin to analyse results, so that parents' views and experiences shape our final results and the guidance we develop. We will also ask their advice to troubleshoot should difficulties arise during the project, for example if recruitment to the project is slower than anticipated in some areas. Details of PPI activities are further described in the detailed plan in individual work packages.

The advisory groups will decide how they will communicate across the project and the extent to which they want to combine activities across the local and national groups.

We will provide training for all parent advisors on the role of research and its life cycle (using PenCRU Family Faculty resources (https://pencru.org), childhood SLCN, SLCN interventions, aims of PPI and the and the tasks involved. We aim for PPI advisory groups to be inclusive and representative of families at risk of SLCN. We will provide additional local training via interpreters if necessary.

In addition to the local and national Parent Advisory Groups, two additional parents will be recruited to the Steering Group that will supervise the conduct of the study.

All PPI advisors' work on the project will be reimbursed at NIHR recommended rates.

Data protection and patient confidentiality

Data from this study will be stored in password-protected electronic files, on Newcastle University servers and only accessed by the research team. Paper files will be stored in a locked filing cabinet within the study site and will be accessible only to the research team. Data will be de-identified to protect participant confidentiality.

See DPIA and Data Management Plan

Indemnity

- The project has been awarded funding by the NIHR Health And Social Care Delivery Research (HDSR) NIHR156329.
- Newcastle University will host the award and manage finances related to it and has reviewed the project to confirm appropriate insurance and indemnity cover.
- Newcastle University will provide insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research.
- Newcastle University will provide insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research.

Access to the final study dataset

Study investigators will have access to the full study dataset following initial analysis. Access to raw data (unanalysed) will be restricted to Chief Investigator and to delegated members of the study team directly involved in each work package. Other members of the research team will have access to anonymised, summarised data.

Anonymised quantitative data from the workpackages including children's language outcomes and health economics data will be made available via ncl.data following publication of our findings, but qualitative data will be not be made available because of the possibility of identification.
Site investigators will be given access to their area qualitative dataset if a formal request describing their plans is approved by the study steering group.

Any requests for access will be discussed on an individual basis by the Research team and agreed by the Study Steering Committee. If access is granted, then a Data Sharing Agreement will be put in place prior to any work or data transfer beginning. All patient documentation will reflect the future use of these data in research.

7 DISSEMINIATION POLICY

Dissemination policy

Newcastle University will own the data arising from the study. On completion of the study, the data will be analysed and synthesised and a Final Study Report prepared. The final report will be uploaded to Realms for review by the NIHR team prior to making results public. The full study report will be accessible via the NIHR Health and Social Delivery Research HSDR Programme.

The Chief Investigator will notify the NIHR prior to submission of any publication or press release (whether in oral, written, or other form, and in particular any press announcement) of the Research or matters directly related to the study. The Chief Investigator or delegated other shall send one draft copy of the proposed publication to the NIHR HSDR Programme via Realms at least 28 days before the date intended for submission for publication.
NIHR HSDR will be acknowledged within the publications and whether they have reviewed and publication rights of the data from the study.

Participants in the study will be provided with the full results via specifically designed newsletters, project website and a study report specifically tailored to the lay person should they consent to this.
The pseudonymised qualitative dataset will be made available following all planned publications by the research team, if we are certain areas cannot be identified. Identification decisions will be taken by research team in consultation with nominated professionals from participating areas.

Authorship eligibility guidelines and any intended use of professional writers

All co-applicants and research associates employed on the project will assist in preparation of the final study report and will be authors of the final study report.

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