Trial Evaluation Protocol Learning Language and Loving It™

NatCen Social Research

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PROJECT TITLE	Hanen Learning Language and Loving It (LLLI)
DEVELOPER (INSTITUTION)	The Hanen Centre
EVALUATOR (INSTITUTION)	National Centre for Social Research
PRINCIPAL INVESTIGATOR(S)	Lydia Marshall
PROTOCOL AUTHOR(S)	Lydia Marshall, Daniel Phillips, Robert Wishart
TRIAL DESIGN	Two-arm cluster randomised controlled efficacy trial with random allocation at nursery level
PUPIL AGE RANGE AND KEY STAGE	3 to 4 years old, Early Years
NUMBER OF SCHOOLS	131
NUMBER OF PUPILS	2,358¹
PRIMARY OUTCOME	British Picture Vocabulary Scale (BPVS)
SECONDARY OUTCOME	Renfrew Action Picture Test (RAPT)

Protocol version history

VERSION	DATE	REASON FOR REVISION
1.0 [original]		
2.0		Trial redesign due to COVID-19 school closures suspending delivery. Redesigned for a new cohort of pupils, removing the baseline attainment test and updating power calculations. IPE design adjusted to address changes to delivery plans (see Appendix 2).

¹ This is an estimate based on expected numbers of pupils and settings. This will be updated once data has been uploaded for the 2020/21 cohort of pupils.

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Intervention

Learning, Language and Loving It™ - The Hanen Program® for Early Childhood Educators (Hanen LLLI) is a training program for early years (EY) practitioners to promote social, language and literacy learning in nurseries. It is a continuing professional development (CPD) program designed to provide staff with practical strategies to enhance children's communication and language skills through specialised ways of interacting and communicating with children during normal daily routines. Hanen LLLI is not widely used in the UK, with a handful of Hanen training programs having been run in the past two years, focusing mainly on a shortened version on Hanen LLLI, called Teacher Talk.

Intervention delivery

Hanen LLLI was developed by The Hanen Centre², based in Canada. In this evaluation the intervention will be coordinated and delivered by Communicate SLT CIC, a speech and language therapy organisation based in the North West of England. Communicate SLT are Hanen-certified trainers for some of the Hanen programs but are otherwise not affiliated in any way with The Hanen Centre.

Mode of delivery

In the original 2019/20 trial plan, delivery of the intervention was scheduled across 31 weeks, including orientation meetings to explain the intervention and evaluation, eight training workshops lasting 2.5 hours each, six individual video feedback sessions per practitioner and a pre-intervention video and post-intervention videos. Due to the Covid-19 pandemic, early years settings closed to all but key worker and vulnerable children in March 2020 and delivery of the training was therefore paused in week 20 with attendance for workshop 6 being affected. The redesign has an additional delivery period of 30 weeks, which means delivery will take place during a total of 82 weeks. Hanen Teacher Talk A will be used to refresh the training content with previous participants and catch-up any new participants who have joined the nurseries in 2020. These workshops will be delivered online in November 2020. Hanen Teacher Talk B workshops will be used for the second part of the revision / catch-up in January 2021 and will be delivered either in-person or online depending on public health guidance at the time. Delivery of workshops 6, 7 and 8, as well as individual feedback sessions will resume in February 2021. All participants will be encouraged to participate in workshop 6 independent of whether they already attended in the workshop during the week of lockdown. As with the original trial plan, an online catch-up workshop will be delivered, replicating each in-person workshop, to accommodate participants who are unable to attend in-person, with an accurate record being kept of attendance at each.

The Hanen LLLI training workshops are delivered to groups of 10-20 practitioners by qualified and Hanen-certified speech and language therapists (SLTs). These SLTs, known as Program Leaders, are fully qualified in the UK and are certified Learning Language and Loving It trainers (LLLI trainer) accredited to deliver the Hanen program. The individual feedback sessions are also led by Program Leaders and usually take place one-to-one in practitioners' own nurseries. However, if national or local Covid-19 related restrictions prohibit visitors in nurseries, then these sessions can also be delivered online. The feedback sessions focus on guided reflection, with Program Leaders providing feedback on videotaped interactions between EY practitioners and children. Practitioners also took part in a further recorded interaction with children at the beginning of the program and will do so again at the end - to establish a baseline level to guide delivery of the intervention and for practitioners' own reflection after the intervention.

The intervention activities are prescribed by The Hanen Centre and non-specified adaptations of the course and training materials and handouts are neither allowed nor encouraged. Minor accepted deviations are detailed in the course handbook for Program Leaders.

² The Hanen Centre's mission is to enable parents and professionals to transform their daily interactions with young children to build the best possible lifelong social, language and literacy skills

Intervention content

Program Leaders are expected to help facilitate the four broad aims of Hanen LLLI:

- Education: provide practitioners with information on language, social and literacy development and on how best to promote these during everyday play activities, conversations and daily routines
- Application: provide practitioners with opportunities to practice and apply strategies and approaches which promote children's development, with feedback from the LLLI Program Leader
- Collaboration: work together with practitioners as they plan and implement individual programmes for children with specific needs
- Peer support: give practitioners the opportunity to share ideas, issues, and concerns with their colleagues

Trainers are instructed to use the 4P teaching cycle while providing training:

- 1. Prepare: Give practitioners a reason for learning by starting with asking them to think about what a particular topic means to them in order to tap into personal experience and interest.
- 2. Present: Present facts and information to deepen or expand knowledge in ways that are interesting, interactive, relevant and enjoyable
- 3. Practice: Create opportunities for practitioners to practice newly learned skills in a variety of hands-on ways with guidance and feedback
- 4. Personalize: Provide opportunities for practitioners to apply and integrate information into their own situation and to generalise into a variety of situations.

During the program, practitioners learn practical strategies for engaging with children to enhance their language development, including for example:

- "OWL" observe, waiting and listening, rather than asking questions
- Using a variety of words and modelling extended language
- Providing opportunities for children to initiate conversation
- Engaging 'reluctant' children in small groups
- · Tailoring language and approach to match children's styles and skills

Study rationale and background

Early language skills are a crucial building block for children's development. Children naturally develop language skills at different rates, but some children fall behind at an early age. Depending on the measures used, 7 to 15 per cent of preschool children are defined as experiencing language difficulties and 14 to 18 per cent do not reach the expected level in the Communication, Language and Literacy domain of the Early Years Foundation Stage (EYFS) Profile (Law *et al.*, 2017). Children from socially disadvantaged backgrounds are, on average, much more likely to experience delays and difficulties.

The importance of language skills is reflected in the EYFS. Reforms to the Early Learning Goals are currently underway in response to a recent review of Reception year which recommended greater focus on oral language and vocabulary development (Ofsted, 2017a).

A key determinant of language development is the amount and quality of language to which a young child is exposed. Given that over 95 per cent of 3-4-year olds participate in formal early education (DfE, 2018a), early years practitioners play an important role. Although the majority (88 per cent) of EY settings are assessed by Ofsted as being good or outstanding (Ofsted, 2017b), the early years workforce is comprised predominantly of Level 3 qualified staff (below degree level) (DfE, 2018b) and recent research points to a downward trend in qualifications (EPI, 2018). It is likely, therefore, that the workforce would benefit from CPD targeted at language.

A recent review of language interventions by Law et al. (2017) recommended further research on the effectiveness of training early years practitioners to deliver programmes within EY settings. The review reported on three studies on Hanen LLLI. An efficacy trial by Girolametto et al. (2003) in which 16 US teachers of 3 to 5-year-olds were randomly assigned to receive training in Hanen LLLI found that pupils engaged in shared reading and playdough activities used a greater number of utterances (d = 1.3; d=1.5), multiword combinations (d = 1.2; d=1.2), and peer directed utterances (d = 0.8; d=0.9). However, the number of different words did not differ by group. Cabell et al. (2011) reported on an RCT of a programme that trained 49 teachers of 3 to 5-year-old kindergarteners in the US in Hanen LLLI. The evaluation found no impact on oral language outcomes but that the treatment group outperformed the control group by 1.5 standard deviations for expressive vocabulary. Piasta et al. (2012) reported on an RCT of a US programme based on Learning Language and Loving It, in which 49 preschool early years practitioners received training. The authors found an impact on total utterances, (d = 3.18), number of different words or NDW (d = 5.30), mean length of utterance, (d = 4.96). Follow up NDW was (d = 2.75). Overall, the review found that Hanen LLLI was particularly promising with high effect sizes (albeit based on low security of findings) for the impact of professional development on EY practitioners' conversational responsivity and children's linguistic productivity and complexity (Law et al., 2017). The authors concluded that the majority of language interventions focus on improving vocabulary, whereas LLLI recognised the importance of conversation and oral narrative.

A handful of Hanen training programs have been run in the UK in the last few years, focusing mainly on a shortened version of Hanen LLLI, called Teacher Talk. As yet, no trials of Hanen LLLI have taken place in the UK. A small-scale pilot evaluation of Hanen LLLI conducted by NatCen Social Research for the EEF found the intervention to be attractive to early years settings and showed evidence of promise regarding changes to practitioners' interactions with children³. The pilot was not powered to investigate impact on children's language and development, which this efficacy trial will seek to measure.

An intervention logic model was developed and finalised as part of the pilot evaluation, and can be found in the Appendix to this protocol.

Impact Evaluation

Research questions

The impact evaluation of Hanen LLLI aims to answer the following research questions:

- What is the impact of Hanen LLLI on the language attainment of 3 to 4-year-olds?
- Does the impact of Hanen LLLI differ by Early Years Pupil Premium status?

Design

The evaluation will be conducted as a two-arm cluster (setting-level) randomised controlled efficacy trial of the effect of Hanen LLLI on the language attainment of 3 to 4-year-olds in nursery settings.

A randomised controlled trial (RCT) uses the mechanism of randomisation to assess the causal impact of an intervention. Randomisation, if conducted correctly, should result in there being no important differences between treatment and control groups in the main determinants of our outcomes of interest. Any differences at baseline are due to chance and are accounted for in the statistical analysis. As a result, any discrepancy in outcomes at the end of the trial can be attributed to the intervention itself. As an efficacy trial, the evaluation aims to test the effect of the intervention in ideal circumstances. Hanen LLLI is designed to enhance children's communication and language skills. The primary outcome of interest is receptive English language as measured by the British Picture Vocabulary Scale (BPVS)⁴ and the secondary outcome provides a further measure of receptive and expressive English Language, as measured by the Renfrew Action Picture Test

³ The EEF project page for the pilot can be found here.

⁴ https://www.gl-assessment.co.uk/media/2308/glassessment-ptm.pdf

(RAPT)⁵. The outcome measures selected to evaluate the effectiveness of Hanen LLLI reflect the fact that changes in vocabulary appear quite early in the intervention's logic model (see Appendix). This choice of outcome measure is also supported by Law *et al.*'s recommendation that an efficacy trial of Hanen LLLI should examine outcomes such as "vocabulary (receptive and expressive), narrative skills, and pre-reading skills" (Law *et al.*,2017: 58).

Nurseries assigned to the control condition will implement a business-as-usual approach to language teaching. An incentive of £1,000 was offered to all control nurseries to participate in the trial. This original incentive is intended to mitigate the risk that nurseries are approached about the trial but choose instead not to participate once assigned to the control group. A further incentive of £250 is being offered to all control nurseries to continue with the extended evaluation with a new cohort of pupils Nurseries will be required to provide background information on all eligible pupils at the start of the academic year in September 2020. This will include Early Years Pupil Premium status, date of birth, pupil first name and surname. We will also collect nursery name, address and postcode, and unique school identifiers. This pupil information will be collected in an Excel spreadsheet template and uploaded by nurseries using a secure NatCen website upload platform.

Trial type an	d number of arms	Two-armed cluster randomised trial
Unit of r	andomisation	Nursery
	ation variables applicable)	Geographic region
Primary	variable	Language attainment
outcome	measure (instrument, scale)	British Picture Vocabulary Scale (BPVS) (receptive language) BPVS raw score
Secondary	variable(s)	Language attainment
outcome(s)	measure(s) (instrument, scale)	Renfrew Action Picture Test (RAPT) (expressive and receptive language) RAPT raw score

Randomisation

Nurseries that agreed to participate in the trial were allocated to one of the two groups using stratified randomisation by geographic region, with a 50:50 ratio of nurseries between treatment and control. Randomisation was stratified by geographic region to help control for possible differences in implementation and thereby decrease the variance of the impact estimator. It was also chosen to help the developer plan Hanen LLLI training by reducing the likelihood that a given region will have an exceptionally high ratio of treatment settings to control settings, or vice-versa. Randomisation was undertaken in Stata and both *do* and *log* files were used to record the randomisation process. At time of randomisation, analysts were blinded to nursery identity. Nursery identifiers were then merged with group allocation data after randomisation. The randomisation of nurseries from the original trial (in the 2019/20 academic year) will be re-used for the 2020/21 trial. This is because Hanen LLLI has already been delivered in intervention nurseries and re-randomising could contaminate the control condition.

Participants

Communicate SLT have identified and recruited eligible nurseries, with NatCen advising on eligibility criteria and communicating the requirements for research participation. Nurseries will upload data on a new cohort of pupils for the 2020/21 academic year, using the same eligibility criteria.

(1) Setting-level eligibility:

a. Only school-based nurseries and maintained nursery schools are eligible to be part of this trial. This selection criterion was introduced to facilitate longitudinal tracking of pupils' outcomes. Pupils in school-based nurseries and maintained nursery schools will have

⁵ http://talkingpoint.org.uk/slts/assessment-children-slcn/expressive-language-assessments

- been allocated a Unique Pupil Number (UPN), whereas pupils attending a PVI setting are less likely to have a UPN.
- b. Nurseries will be given a recommendation of signing up two-thirds of staff working with 3 to 4-year-olds to take part in Hanen LLLI, but the minimum requirement will be that at least 50 per cent of eligible practitioners including a teacher should be able to participate.
- c. No more than 50 percent of practitioners in a nursery should have previously participated in a similar Hanen intervention named 'Teacher Talk' and none should have previously participated in Hanen LLLI.
- d. Nurseries should have around fifteen 3-4-year-olds to be included in the trial sample. However, there may be a few nurseries that have only twelve 3-4 year olds.

(2) Practitioner-level eligibility:

- a. Participating practitioners should not have taken part in Teacher Talk.
- b. Other than this, nursery managers will be able to select practitioners to take part on any basis and will identify the staff who will take part in the program if they are randomised to the treatment group *before* randomisation. The IPE will explore the criteria that managers use to select staff to participate in the program.

By the autumn term of 2019, all participating nurseries completed a Memorandum of Understanding (MoU) which included institutional consent to be involved in the study. An addendum will be sent to schools in the Autumn term of 2020, outlining the new evaluation requirements. Participating nurseries will be required to inform parents of all prospective eligible 3-4-year-olds about their nursery's participation in the trial by letter. A research information sheet and privacy notice will be supplied by NatCen explaining that nurseries' access to the program will be allocated at random and that participation in the evaluation will involve the collection and processing of children's personal data. Once parents have been informed, nurseries will be requested to enumerate 3-4-year-old children. All pupils in intervention settings will access the intervention. In the original design, seventeen children were randomly sampled from all 3 to 4-year-olds in that nursery to be tested at baseline and endline⁶. In order to reduce burden on settings no baseline test will be conducted with the new cohort of 3-4-year-olds. To compensate for the loss in power arising from the smaller number of participating settings, up to 20 pupils per setting will be tested at endline for the 2020/21 redesign. We will schedule 'mop-up' testing sessions to test any pupils absent on the first date of testing.

Sample size calculations

Table 1 Sample size calculations

Original design Redesign **OVERALL** EYPP⁷ **OVERALL EYPP MDES** 0.19 0.22 0.30 0.37 0.36 0.36 0.00 0.00 Pre-test/ posttest correlations level 2 (school) 0.18 0.18 0.00 0.00 Intracluster correlations level 2 (school) 0.15 0.15 0.15 0.15 (ICCs) Alpha 0.05 0.05 0.05 0.05 **Power** 0.80 0.80 0.80 0.80 One-sided or two-sided? 2 2 2 2

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⁶ In nurseries with fewer than 17 pupils aged 3-4, all eligible pupils were included in the sample.

⁷ We note that EEF protocols usually include sub-group analysis by Free School Meal (FSM) status. However, we use Early Years Pupil Premium (EYPP) here in preference to FSM as EYPP data is available directly from settings, whereas FSM is not. EYPP provides schools with additional funding for all 3-4 year-olds from low-income families. All EYPP pupils are also eligible for FSM.

Average cluster size*		17	2	18	2
	Intervention	70	70	65	65
Number of schools	Control	70	70	66	66
	Total	140	140	131	131
	Intervention	1,190	169*	1,170	132*
Number of pupils	Control	1,190	169*	1,188	130*
	Total	2,380	338*	2,358	262*

^{*}Proportion of FSM pupils anticipated to be national average for age group (nursery and primary school age) of 14.2%, as in DfE (2018c).

The Hanen LLLI trial intended to incorporate 140 nurseries, with 70 randomly allocated to a treatment condition in which nurseries receive the Hanen LLLI intervention and the other 70 randomly allocated to a 'business as usual' control condition. Communicate SLT aimed to over-recruit by 5% (n=147) in order to allow for any pre-baseline drop out over the summer break.

Communicate SLT approached 861 settings, recruiting 147 to the Hanen LLLI trial.⁸ In August 2019, 73 settings were randomly allocated to a treatment condition in which nurseries receive the Hanen LLLI intervention while the remaining 74 were randomly allocated to a 'business as usual' control condition. Since randomisation, sixteen schools dropped out of the evaluation, fifteen prior to baseline testing (seven intervention; eight control) and one intervention school after baseline testing. Although these settings had already been randomised, they (and the developers) were blind to their allocation at the point at which they dropped out of the evaluation.⁹ The intention-to-treat sample therefore consists of 65 intervention settings and 66 control settings.

For education programmes, the variance explained by pre-test scores can be relatively high if pre-test scores are used in adjusted analysis (Bloom *et al*, 2007). This increases statistical power, making it easier to detect small effects. Language attainment was collected at baseline for the 2019/20 cohort of pupils. Whilst the original design included a baseline test, the redesign does not. This decision was taken because of the burden it would place on schools and pupils in the first term back (for many schools and pupils) since schools closures in 2019/20. There is therefore no measure of baseline attainment in the model. School-level intra-cluster correlations (ICCs) draw on the ICCs found by Husain *et al.*'s (2018) Family Skills evaluation (.15 class-level and .02 school-level ICCs), together with information provided in Demack's (2019) paper exploring ICCs for early years programmes.

The calculations were undertaken using PowerUp! and indicate that this study is powered to detect an effect of 0.23 standard deviations based on the above assumptions. The calculations do not account for possible attrition over the course of the evaluation.

Outcome measures

The primary outcome of interest is English language ability, measured using the British Picture Vocabulary Scale (BPVS). BPVS tests a child's receptive vocabulary by asking children to identify pictures that illustrate a given word's meaning. The BPVS will be collected at endline towards the end of the summer term 2021¹⁰ by Speech and Language Therapists and Early Years Consultants (SLTs).

The Renfrew Action Picture Test (RAPT) will be analysed as a secondary measure of attainment. RAPT uses pictures to test children's receptive and expressive language by asking them to describe pictures that they are shown. It will be collected at endline by SLTs at the end of the summer term in

⁸ Three settings dropped out prior to randomisation and were replaced with settings on a waiting list. 9 These schools are not considered in the intention-to-treat sample. These cases will therefore not be included in estimates of attrition.

¹⁰ Nurseries will not be informed of the baseline outcome but can opt to receive endline results after endline testing.

2020. In providing a measure of expressive, as well as receptive, language, RAPT offers an assessment of an outcome slightly further along the causal chain contained within the intervention's logic model.

SLTs will administer and mark both tests¹¹. SLTs will not be directly informed of nurseries' treatment allocation. However, at endline nursery staff will know of their treatment allocation and therefore it will not be possible to ensure SLTs are blinded to treatment allocation when administering and marking endline tests.

Analysis plan

Hanen LLLI will be evaluated as a two-level, cluster randomised control trial. The outcomes of pupils in nurseries allocated to Hanen LLLI will be compared with pupils in nurseries allocated to 'business as usual' nurseries. The primary analysis will evaluate the impact of the intervention on an in intention-to-treat (ITT) basis using the BPVS endline raw score as the primary outcome measure, as per the latest EEF Analysis Guidance (Education Endowment Foundation, 2018).

To account for the clustering of pupils within nurseries, the impact will be estimated using a two-level multilevel regression model with pupils at level one and nurseries at level two. The BPVS endline raw score will be regressed on a binary indicator of treatment allocation, geographic region, and will include a random effect to account for the variance at school level. The analysis of the secondary outcome, the Renfrew Action Picture Test (RAPT), will follow the same approach as that for the primary outcome.

For both primary and secondary outcomes, the impact will be presented as a Hedge's g effect size, accounting for the clustering of pupils in schools with 95% confidence intervals (Hedges, 2007).

One sub-group analysis will be conducted, exploring if Hanen LLLI has a differential impact depending on a pupil's Pupil Premium (EYPP) status. To analyse impact by EYPP status, a similar model to that described above will be estimated, with the addition of a binary indicator of EYPP status interacted with the treatment allocation indicator. If a significant relationship is identified, a separate model will be estimated to explore differential effects for pupils eligible for EYPP.

¹¹ Hanen LLLI also uses Speech and Language Therapists as Program Leaders to lead the training of staff. Different SLTs will administer the tests from those who will act as Program Leaders.

Implementation and process evaluation

A process study will be carried out alongside the impact study to address the following research questions:

- How is Hanen LLLI delivered, and what are the facilitators and barriers to delivery?
- What are the perceived benefits of the program for EY practitioners, nurseries and children?
- What is the per-pupil cost of the intervention?

The key dimensions of implementation that will be assessed are: fidelity (including dosage, quality, and adaptation), reach, responsiveness and usual practice (programme differentiation and monitoring of control). The table in Appendix 2 sets out all changes to the original IPE design.

Table 2 shows how the IPE methods will address each of these dimensions. The table in Appendix 2 sets out all changes to the original IPE design.

Table 2 IPE domains and methods

Domain	Method					
	Workshop observations	Interviews with nursery staff	Site visits	Program Leader interviews	Nursery staff surveys	Attendance registers
Fidelity						
Dosage						
Quality						
Adaptation						
Reach						
Responsiveness						
Usual practice						

Methods

We propose a mixed-method approach, designed to gather both breadth of data through surveys and depth through qualitative interviews, observations and site visits.

Observations of the Hanen LLLI program

We will conduct observations to gather information on the coverage and delivery of the Hanen LLLI program and practitioners' responsiveness to it [fidelity, quality, responsiveness, adaptation].

We observed six of the Hanen LLLI training workshops in 2019/20 and will observe 4-6 more in 2020/21. Overall, the workshops will be selected to ensure that a number of Program Leaders are included in the observations and that the observations include the first and final workshops, the two 'review workshops' at the start of the 2020/21 school year, plus at least two more sessions through the course. We will aim to observe two or more Program Leaders delivering the same workshops, in order to capture variation and adaptation.

We will observe video feedback sessions during the nursery visits (see below).

Interviews with nursery staff

We will conduct interviews with senior staff at treatment nurseries to understand how nurseries participate in Hanen LLLI, barriers and facilitators to delivery and perceived impacts. We will also conduct interviews with staff in control nurseries to understand usual practice and how this compares with the strategies encouraged by the Hanen LLLI program.

- Early implementation interviews (n=11) were conducted with treatment nurseries in the autumn term 2019 to gather contextual information on the nursery and their practice [usual practice], how the nursery planned support staff to attend workshops (including planning cover) [responsiveness], and any challenges anticipated during the intervention. Interviews were conducted with senior members of staff (nursery teachers or managers) via telephone and lasted approximately 30 minutes.
- Redesign interviews (n=6-8) with treatment nurseries in the autumn term 2020 will explore the consequences of the revised delivery timetable for nurseries, including plans for resourcing. They will also explore the impacts of the Covid-19 school closures and any implications for engagement with the intervention. Interviews will be conducted with senior members of staff (nursery teachers or managers) via telephone and last approximately 30 minutes. We will aim for around half of these interviews to be with nurseries who took part in IPE activities in 2019/20, to allow for longitudinal understanding of the impacts of the redesign.
- Ongoing delivery interviews (n=6-8) with treatment nurseries in the spring term 2021 will explore how delivery of the Hanen LLLI workshops and training has been progressing [quality], any cascading of Hanen LLLI principles to non-trained staff [reach], and perceived impacts on staff practice, the nursery environment and children [responsiveness]. They will also gather data on whether practitioners and nurseries intend to continue implementing Hanen LLLI principles beyond the end of the trial. Interviews will be conducted with senior members of staff (nursery teachers or managers) via telephone and last approximately 40 minutes. We will aim for around half of these interviews to be with nurseries who took part in early implementation or redesign interviews.
- Business as usual interviews (n=9-11) with control nurseries will gather data on usual practice in nurseries, including engagement with any communication and language development interventions. Interviews will be conducted with senior members of staff (nursery teachers or managers) via telephone and last approximately 30 minutes. Three interviews were conducted in 2019/20. Six to eight more will be conducted in 2020/21, including if possible three follow-up interviews with the nurseries interviewed the previous year. This will allow for longitudinal monitoring of the control conditions and help us to understand the implications of Covid-19 and the school closures.

IPE site visits

To gain an in-depth understanding of how the intervention is being experienced and delivered by practitioners and nurseries, we conducted seven visits to treatment nurseries using qualitative methods (interviews and observations) in the 2019/20 academic year. The site visits included:

- Observation of video feedback sessions (1 per site visit)¹² to understand the content of these sessions [fidelity, quality, adaptation], practitioners' responsiveness, and any barriers and facilitators to delivery.
- Interview with senior staff member (nursery teacher or manager 1 per site visit) to
 understand barriers and facilitators to ongoing engagement with Hanen LLLI, barriers and
 facilitators to success and perceived impacts (positive and/or unintended) for staff practice,
 the nursery environment and children's language and communication development [reach,
 quality, responsiveness].

¹² Where nursery timetables allow we will schedule site visits to coincide with video feedback sessions. We anticipate that this will not always be possible but will conduct a minimum of six observations.

• *Interview(s) with trained practitioner(s)* (1-2 per nursery) to understand *responsiveness* to the intervention, barriers and facilitators and perceived impacts.

In addition to the site visits, we will carry out 4-6 observations of the 'post'-video feedback sessions that will take place in the spring term 2021, which are a new addition to the intervention resulting from the extended delivery timetable. If possible, these will be conducted at the same nurseries visited during the academic year 2019/20.

Interviews with Program Leaders

We understand that there will be around 7-13 Program Leaders delivering Hanen LLLI in the trial. We interviewed six Program Leaders in the spring term 2020 to provide evidence on the delivery of training and video feedback [fidelity], any variations in delivery [adaptation] and perceived acceptability and perceived impacts of the program [responsiveness, reach] and recommendations for intervention improvements from the perspective of these expert trainers. These interviews lasted approximately 45 minutes and were conducted by telephone.

We will conduct 4-6 further interviews with Program Leaders in 2020/21 to understand the implications of the redesign from Program Leaders' perspective. These interviews will help us to understand how delivery has changed, challenges and opportunities raised by the two-year delivery and perceived impacts. They will also explore *perceived impacts* towards the end of the revised delivery timeline.

Staff surveys

We will conduct a short post-intervention web survey of staff who have taken part in Hanen LLLI in the summer term 2021. The survey will gather practitioner feedback on the intervention [responsiveness, reach] and data on barriers and facilitators and perceived impacts for staff and children. For participants with a management role in their nursery, we will also ask about the consequences of Covid-19 and the school closures for delivery of Hanen LLLI and for the nursery and children more generally.

We will conduct a web survey of control nursery managers in Spring 2021 to understand *usual practice*, monitor the control and understand the consequences of and responses to Covid-19 in the control group.

IPE sampling

We will sample nurseries to take part in qualitative research activities using a purposive approach in order to achieve a diverse sample in terms of factors expected to affect practitioners' and nurseries' experiences of the Hanen LLLI program. This will include contextual nursery-level data (e.g. size, local authority) and – for later activities – findings from early IPE interviews. As described above, our sampling strategy will entail some longitudinal follow up, to allow both breadth and depth of understanding across and within nurseries. Intended sample sizes for each qualitative activity are given above.

All IPE surveys will be sent to all participating nurseries in the relevant group (treatment or control). The practitioner survey will be sent to all practitioners in treatment nurseries who were nominated to take part in the Hanen program.

Analysis

All qualitative interview data will be digitally recorded with permission from participants and professionally transcribed. The transcribed data will be managed and analysed using the Framework approach, developed by NatCen (Ritchie *et al.* 2013) and embedded in NVivo. Key topics emerging from the data will be identified through familiarisation with the transcripts. An analytical framework will be drawn up and a series of matrices set-up, each relating to a different thematic issue. The columns in each matrix represent the key sub-themes or topics and the rows represent individual participants. Data will be summarised and categorised systematically by theme. The final analytic stage will then involve drawing out the range of experiences and views from the charted data and identifying

similarities and differences across and within participant groups and individual nurseries. Descriptive and cross-tab analysis of survey data will be conducted using SPSS. Triangulation of all data and thematic synthesis by the main implementation domains will provide a comprehensive assessment of implementation and help to explain the impact evaluation findings.

Compliance

A measure of compliance will be constructed according to staff attendance at Hanen LLLI training. The Hanen LLLI program includes eight training sessions and six individual feedback sessions, which focus on guided reflection, with Program Leaders providing feedback on videotaped interactions between EY practitioners and children. To be eligible to take part in the intervention, a nursery must be able and agree to release a minimum of 50% of its eligible staff for the training. 'Staff' includes nursery teacher(s), plus nursery nurses, teaching assistants (Tas), and/or other more senior staff.

Attendance at training will be captured via a register designed by NatCen and completed by Communicate SLT.

A measure of compliance will be constructed as follows:

- Nurseries will be given one point for each session (where a session can be: the eight training workshops, the orientation session, the six individual video feedback sessions, or the baseline and post video sessions) attended by a teacher, up to a total of seventeen.
- Two further points will be awarded to any nursery where the head-teacher (or equivalent) attends at least one training workshop.
- Nurseries will be awarded further points for the proportion of sessions (where a session can be either the eight training workshops or the six individual video feedback sessions) attended by any additional¹³ staff who have been nominated to attend training, up to a total of four points. The proportion of sessions attended on average by any additional nominated staff will be used to calculate additional points. For example, if average additional staff attendance for a particular nursery is 25 per cent or more, the nursery will be awarded an additional one point (≥ 50%, 2 points; ≥ 75%, 3 points; 100%, 4 points).

The total score will then be summed to produce a scale of compliance with a possible range of $0 \le Comply_A \le 23$.

This data will also be used to assess dosage and reach for the IPE.

Cost evaluation

We propose to collect cost data consistent with EEF guidelines¹⁴. There will be two sources of cost data:

- Cost-proforma sent to Communicate SLT to calculate the cost of delivering the Hanen LLLI workshops, video feedback sessions and any other support for nurseries.
- Short web form sent to nursery leads/school bursars to gather data on the costs of participation that fall on nurseries, such as the hours of supply cover needed for staff to attend workshops.

Findings from the pilot will inform the development of the templates for this data collection. The per pupil cost over three years will be estimated on the basis of annual average net costs to nurseries divided by the number of participating children.

¹³ Not including the nominated teacher or the head-teacher or equivalent.

¹⁴https://educationendowmentfoundation.org.uk/public/files/Evaluation/Setting up an Evaluation/Cos t_Evaluation_Guidance_2019.12.11.pdf

Ethics and registration

NatCen's research information leaflet setting out the evaluation requirements for the evaluation will be sent to nurseries at recruitment stage. Nurseries that sign an MoU will send out a parent information leaflet to parents/carers of all eligible children. The information leaflet will explain the study; the research activities for the trial (including testing), data linkage to the National Pupil Database (NPD), the transfer and storage of anonymised data to the EEF's archive. Parents/carers will be able to object to their child's data being used for the evaluation at any point during the study by contacting the nursery or NatCen. NatCen will maintain a database of withdrawals and delete the appropriate level of pupil data as soon as a withdrawal is communicated.

Ethical approval for this study was obtained from NatCen's Research Ethics Committee in advance of research activities in the autumn term of 2019. The NatCen REC reviewed the study design to confirm compliance with internal ethical standards. The NatCen REC will also approve the changes to the design set out in this protocol.

The trial will be registered with the International Standard Randomised Controlled Trial Number (ISRCTN).

Data protection

NatCen will store and handle all data securely and confidentially in line with the GDPR. Only the research team and approved third parties listed in the privacy statement (e.g. transcription agency, speech and language therapists conducting testing) will have access to the data collected as part of the evaluation. School and pupil-level data will be transferred to NatCen via a secure FTP. Reports and other publications arising from this research will not identify any individual nursery, staff member, or pupil. Nurseries or individual staff who no longer wish to take part in the evaluation can request to have their data deleted at any point prior to the submission of the draft report.

NatCen will be the data controller and will additionally process data. The legal basis for processing the data is 'legitimate interest'. NatCen will process the data for the legitimate purpose of conducting the evaluation of Hanen LLLI. No special category data will be collected as part of the evaluation. We will issue a privacy notice to all concerned parties, which will also be published on the study website.

All data will be securely deleted from NatCen's network six months after the end of the project.

Personnel

The intervention will be coordinated and delivered by Communicate SLT CIC, a speech and language therapy organisation based in the North West of England.

Table 3 Communicate SLT personnel

Delivery team		
Caroline Coyne	Director of HR and Operations	Project lead
Joanne Burr	Director of Finance and Business Development	Quality control
Lisa Chetter	Project manager	Project manager
Rhian Owen	Program Leader supervisor	Program Leader Supervisor
Sally Wiseman	Program Leader	Speech and Language Therapist
Elizabeth Evans	Program Leader	Speech and Language Therapist
Kathryn Burkmar	Program Leader	Speech and Language Therapist

Adele Banton	Program Leader	Early Years Consultant
Jenny Kenrick	Program Leader	Speech and Language Therapist
Ann Shellard	Program Leader	Early Years Consultant
Kathryn Barker	Program Leader	Early Years Consultant
Sue Paul	Program Leader	Speech and Language Therapist
Vicki Maughan	Program Leader	Speech and Language Therapist

The evaluation will be led by NatCen's Children and Families Team, who will work closely with impact evaluation experts in NatCen's Evaluation Team. Speech and Language Therapists and Early Years Consultants will be recruited by NatCen to conduct the assessments with children.

Table 4 NatCen personnel

Children and Families Team				
Dr Lydia Marshall	Research Director	Principal Investigator. Overall study lead. Senior oversight of IPE.		
Dr Jonah Bury	Senior Researcher	Project Manager, IPE and testing.		
Harriet Read Emily Roberts Molly Mayer Helen Burridge Phoebe Averill	Researchers	Working on all study stages and testing.		
Evaluation Team				
Robert Wishart	Research Director	Lead on impact evaluation.		
Ben Stocker	Researcher	Working on impact evaluation.		

Risks

The main risks to this project will be low participation in the trial, low take up and compliance with the intervention, risks associated with schools not complying with the random allocation, and low response rates in the post-intervention pupil testing. NatCen will maintain a detailed risk register throughout the life of the project and manage risks on an on-going basis.

Table 5 Preliminary risk register

Risk	Likelihood / impact	Mitigation / Contingency
	Likelihood: Medium	Communicate SLT CLC will need to recruit 140 nurseries schools. NatCen will provide clear, concise information on the
Difficulties recruiting the required number of suitable school nurseries	Impact: High	evaluation requirements for communication with schools and be on hand to answer questions at the MOU signing stage. NatCen will also have a dedicated website and contact email/phone number to ensure the study is legitimate. Regular updates from Communicate to facilitate progress monitoring. Communicate will "over-recruit" up to 5% additional schools to allow for dropout over the summer holidays.
	Likelihood: Medium	Low levels of compliance (i.e. nursery staff not attending training sessions or feedback sessions) may result in lack of statistical power for the impact analysis.
Low levels of compliance among nurseries	Impact: High	NatCen will draft clear information leaflets for the evaluation, outlining required activities. Communicate SLT CLC will meet face-to-face with all nurseries in advance of the implementation delivery to fully explain the programme and answer any questions.
		Program Leaders will be trained in engaging nursery staff and will report any issues with attendance to Communicate SLT.
Nursery level	Likelihood: Low	This will be addressed by setting out clearly the requirements for the trial in the MoU; communicating the financial incentive
attrition	Impact: High	for control nursery clearly and providing nurseries with clear instructions at the start of the project on what needs to be done and when.
B 71 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Likelihood: Low	Pupil absence during testing and pupils leaving nurseries during the school year could both lead to pupil level attrition.
Pupil level attrition	Impact: Medium	Speech and Language Therapists will carry out mop up visits to ensure that as many children as possible are tested in each nursery at baseline and endline.
	Likelihood: Medium	Research activities involved for the evaluation will be clearly outlined in the MoU.
Nursery staff unable to find the time for interviews	Impact: Medium	NatCen researchers are experienced in making appointments for observations and interviews. Most interviews will be conducted by telephone to ensure flexibility and convenience for nursery staff. Different nurseries will be sampled for the case study visits to avoid over-burdening nurseries.
Covid-19 disrupts	Likelihood: Medium	Revision sessions to address disruption in 2019/20 academic year. Online catch-up sessions for individual participants unable to
program delivery	Impact: Medium	attend training workshops in person in 2020/21. Option for online delivery of workshops and video feedback sessions for all participants.

Covid-19 disrupts	Likelihood: High	Interviews conducted by telephone. Observations can be replaced with remote video observation.
data collection	Impact: High	No testing until Summer 2021. Contingency of longitudinal follow up at EYFS/Key Stage 1 instead of data collection in 2021.

Timeline

Table 6 Evaluation timeline

Dates	Activity	Staff responsible/ leading
Jan 2019 – Mar 2019	Finalise recruitment materials	Communicate SLT NatCen
Mar 2019 – Jun 2019	Recruit nurseries, sign MOUs Schools nominate staff to take part in LLLI	Communicate SLT
Jul 2019 – Aug 2019	Randomisation	NatCen
Oct 2019	Baseline assessments Schools informed of randomisation (after testing)	NatCen
Nov 2019 – May 2021	Intervention delivery	Communicate SLT
Nov 2019 – May 2021	Workshop and video-feedback session observations	NatCen
Dec 2019	Early implementation interviews	NatCen
Jan 2020 – Mar 2020	Case study visits Interviews with Program Leaders (1 st round) Business as usual interviews (1 st round)	NatCen
Nov 2020	Parent information leaflets handed out Pupil lists for new cohort sent to NatCen	Nurseries NatCen
Nov 2020	Interviews with Program Leaders (2 nd round)	NatCen
Dec 2020	Redesign interviews	NatCen
Jan 2021 – Feb 2021	Ongoing delivery interviews Business as usual interviews (2 nd round)	NatCen
Mar 2021	Control nursery survey	NatCen
Jun 2021 – Jul 2021	Endline assessments Treatment nursery survey Cost data collection	NatCen
Jul 2021 – Nov 2021	Analysis and reporting	NatCen
Nov 2021	First draft of the report submitted to the EEF	NatCen
Spring 2023	TO BE DISCUSSED AND POTENTIALLY COMMISSIONED SEPARATELY: Addendum report on EYFS attainment: Spring 2023	NatCen

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Trial Evaluation Protocol Learning Language and Loving It™

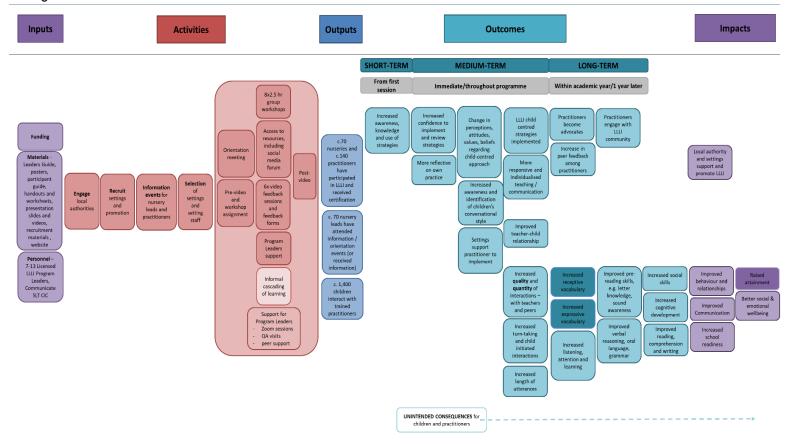
NatCen Social Research

Template last updated: March 2018



Appendix 1: Intervention logic model

Learning Language and Loving It $^{\text{TM}}$ - The Hanen Program® for Early Childhood Educators Logic Model



Appendix 2: Changes to IPE design

Original proposed research activity	Activity completed in 2019/20	Planned activity for 2020/21	Rationale
Training workshop observations (n=8-12)	Observed 6 workshops	Observe 4-6 more workshops	It is important to observe the new 'review' workshops (which are not a part of the standard LLLI intervention) as well as to observe the final workshops as per the original protocol.
Business as usual interviews with managers of control nurseries (n-6-8)	Completed 3 interviews	Conduct 6-8 more interviews, including follow up interviews with the nurseries already interviewed	Conducting interviews with more control nurseries will be important to allow diversity in the achieved sample and to understand any differences between 2019/20 and 2020/21 (including impacts of Covid-19). Conducting follow-up interviews will allow for longitudinal monitoring of control conditions.
Video feedback session observations (n=8-12)	Observed 8 sessions	Observe 4-6 more sessions	These observations will be focused on the two video sessions that will be conducted after the LLLI training finishes (which are not a part of the standard LLLI intervention).
Ongoing delivery interviews with managers of treatment nurseries (n=10-12)	N/A – postponed due to school closures	 Conduct a total of 12-16 interviews: 6-8 towards beginning of delivery to address redesign – plans for resourcing, perceived implications 6-8 towards end of intervention to capture ongoing delivery 	The interviews towards the end of the intervention will fulfil the original aim of the ongoing delivery interviews – to capture perceived impacts and understand whether and how the Hanen strategies will be adopted into everyday practice in the treatment nurseries. The interviews towards the beginning of delivery will be important in helping us to understand the consequences of the revised delivery timetable, including plans for resourcing if staffing has changed. They will also explore the impacts of the Covid-19 school closures and consider any implications for engagement with the intervention.

Original proposed research activity	Activity completed in 2019/20	Planned activity for 2020/21	Rationale
Interviews with program leaders (n=4-6)	Interviewed 6 program leaders	Conduct 4-6 more interviews to directly address the implications of the redesign	These interviews will help us to understand how delivery has changed, challenges and opportunities raised by the 2-year delivery and perceived impacts.
Web survey of practitioners (to compare practice in treatment and control nurseries)	N/A – postponed due to school closures	Conduct a practitioner survey with practitioners in treatment nurseries only	The survey was initially intended to compare practice in treatment and control nurseries. However, we expect that our ability to conduct this analysis will be impaired by low response in control schools (due to disengagement over the two years) as well as any nursery-level attrition resulting from the extended trial timetable. Instead we will develop a more detailed questionnaire to gather practitioners' perspectives on the intervention and perceived impacts.
Web survey of nursery managers (to collect information about the costs of the intervention from treatment nurseries only)	N/A – postponed due to school closures	 Conduct two, more detailed surveys: A survey of treatment nurseries to ask about costs, perceived impacts and the consequences of Covid-19 (combined with practitioner survey above) A survey of control nurseries to monitor the control and ask about the consequences of Covid-19 	These surveys will enable us to investigate the consequences of the Covid-19 outbreak on both treatment and control nurseries and consider whether the intervention has affected nurseries' ability to cope with these consequences (positively or negatively). The extended delivery timetable makes it more important to monitor control conditions, as control nurseries may have sought out additional interventions or support in this new academic year.