E-PLAYS-2 (Enhancing Pragmatic Language skills for Young children with Social communication impairment) trial

Evaluation of a computerised intervention to promote communicative development and collaborative skills in children

Study Protocol

Funded by NHS National Institute for Health Research

Protocol date: v1.1 19th June 2023

Chief Investigator: Dr Suzanne Murphy

Sponsor: University of Bedfordshire

Funder: NIHR Public Health Research

Clinical Trials Unit: York Trials Unit, University of York

ISRCTN 17561417

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Protocol Version Number: 1.1

GENERAL INFORMATION: Study sponsor contact: Professor Gurch Randhawa, University of Bedfordshire.

Signature Page

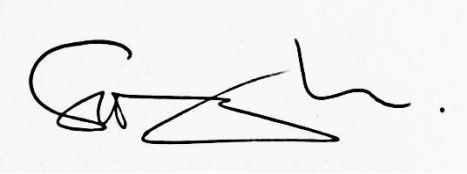
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

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 clinical investigation without the prior written consent of the Sponsor.

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

Authorised by:

Name: Dr Suzanne Murphy
Signature:



Role: Chief Investigator
Date: 10th July 2023

Name: Professor Gurch Randhawa
Signature:

Role: Sponsor Representative
Date: 11th July 2023

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Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	v1.1	19.06.2023	Suzanne Murphy, Lyn Robinson-Smith, Charlie Welsh, Kate Hicks.	New section: Sample Size Calculation_ Revised. Internal pilot recruitment figures added. Updates to TSC membership. Minor updates to child and school eligibility criteria. Further clarification provided on school recruitment, and on the child recruitment and consent strategy within schools. Further detail provided for primary and secondary outcome analysis, and procedures to account for missing or spurious data. Additions to ethics and regulatory considerations. Updates to adverse events reporting procedure and safeguarding procedure. Streamlining of data management process.

All protocol amendments to be listed here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the funder for approval prior to submission to the ethics committee.

Contents

Abbreviation List and Glossary

AE	Adverse event
CACE	Complier average causal effect
CCC-2	Children's Communication Checklist
CEAC	Cost-effectiveness acceptability curve
CELF-5	Clinical Evaluation of Language Fundamentals-5
CHU-9D	Child Health Utility questionnaire
CI	Chief Investigator
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DSA	Data Sharing Agreement
EAL	English as an additional language
ECHP	Education, Health and Care Plan (outlining special educational needs)
ERRNI	Expression, Reception and Recall of Narrative Instrument
E-PLAYS-2	Enhancing Pragmatic Language skills for Young children with Social communication impairment (2)
EQ-5D-Y	European Quality of Life-5 Dimension (youth version)
FSM	Free School Meals
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ICC	Intraclass correlation coefficient
ISRCTN	International Standard Randomised Controlled Trials Number
ITT	Intention To Treat
MAR	Missing at random
MRC	Medical Research Council
MOU	Memorandum of Understanding
NHS	National Health Service
NIHR	National Institute for Health Research
PIS	Participant Information Sheet
PSSRU	Personal Social Services Research Unit
QALY	Quality-Adjusted Life Year
RA	Research Assistant
RCT	Randomised Controlled Trial
SAE	Serious Adverse event
SCD	Social communication difficulties
SD	Standard Deviation
SENCO	Special Educational Needs Co-ordinator
SEND	Special education needs or disability
SD	Standard deviation
SDQ	Strengths and Difficulties Questionnaire
SOP	Standard Operating Procedure
TA	Teaching Assistant
TMF	Trial Master File

TMG	Trial Management Group
TPS	Test of Pragmatic Skills
TSC	Trial Steering Committee
UK	United Kingdom
YTU	York Trials Unit

Trial Summary

Trial Title	Enhancing Pragmatic Language skills for Young children with Social communication impairment trial; evaluation of a computerised intervention to promote communicative development and collaborative skills in children
Acronym	E-PLAYS-2
Protocol Version (Date)	Version 1.1 19.06.2023
ISRCTN	ISRCTN17561417
NIHR PHR number	NIHR131745
Study Design	Pragmatic cluster-randomised controlled trial with an internal pilot comparing care as usual plus E-PLAYS-2 versus care as usual, outcomes up to 40 weeks
Study Duration	48 months
Study Participants	Primary school children with social communication difficulties aged 5-7 years-old (Years 1 & 2)
Planned Sample Size	88 schools - approximately 400 focal children
Interventions to be evaluated	E-PLAYS, a computerised language programme
Intervention duration	Ten weeks (30 minutes per week for ten weeks)
Follow-up duration	35-40 weeks post-randomisation
Planned Trial Period	12 months internal pilot, 12 months full trial
Primary outcome measure	*Completed by a blinded, independent research assistant at 35-40 weeks post-randomisation with focal children only* Test of Pragmatic Skills (TPS)
Secondary outcome measure(s)	*Completed by a blinded, independent research assistant at 15-20 weeks post-randomisation with focal children only* • TPS *Completed by a blinded, independent research assistant at 15-20 and 35-40 weeks post-randomisation with focal children only* • Clinical Evaluation of Language Fundamentals-5 (CELF-5, Recalling Sentences and Following Directions subscales) • Expression, Reception and Recall of Narrative Instrument (ERRNI) • Droodles • Communication Test • Director's Task
	Completed by the parent/carer at 15-20 and 35-40 weeks post-randomisation for focal children only: • Child Health Utility (CHU-9D, parent questionnaire) • The European Quality of Life (EQ-5D-Y, proxy version 1) • Bespoke resource use parent/carer questionnaire

	Completed by the teacher at 15-20 and 35-40 weeks post-randomisation for focal children only • Children's Communication Checklist (CCC-2) • Strengths and Difficulties Questionnaire (SDQ)
	Completed by a blinded, independent research assistant at 15-20 and 35-40 weeks post-randomisation with 88 randomly selected partner children only • TPS

Introduction

Background

Children who have difficulties with social communication (also known as pragmatic language ability) experience problems with using language for social purposes. Whilst their knowledge of grammar and vocabulary may be adequate or even advanced, they struggle with communicative tasks such as appropriate use of greetings, conversational turn-taking, understanding non-literal language such as jokes, irony or sarcasm, social conventions such as politeness, taking the perspective of their listener and responding with relevant information (American Speech-Language-Hearing Association, 2015).

'Social communication difficulties' (SCDs) or 'pragmatic language impairments' represent a continuously distributed trait in the population. This trait includes individuals at the extreme end who are diagnosed with autistic spectrum disorder or severe language disorders but a much larger group show milder, but still detrimental, communication difficulties (Skuse et al., 2009).
Children with SCDs are commonly rejected and victimised by peers (Laws, et al., 2012, Mok et al., 2014) and around 40% of boys are severely disruptive (Ketelaars et al., 2010, Donno et al., 2010, Gilmour et al., 2004). In groups, they fail to contribute appropriately, and are often ignored or dominated by peers (Brinton et al., 2000, Murphy et al., 2014a). Children with language problems experience lower quality of life; in adulthood these individuals experience more mental health problems (anxiety/depression), lower academic achievement and make fewer friends (Whitehouse et al., 2009). Health economic evaluations have also been called for as healthcare costs have been shown to be 36% higher for children with language disorders at age 4-5 years-old (Sciberras et al., 2015).

These communication difficulties frequently cause troubled interactions with family, peers, teachers and the criminal justice system (Kelly et al., 2017, St Clair et al., 2019). For primary school children of low socio-economic status, pragmatic language skills in particular appear to be especially important (Law et al., 2014). In spite of these negative outcomes, language impairments as a whole remain little known by the public and under-researched by comparison to conditions with similar prevalence and impact such as childhood obesity and dyslexia (Bishop, 2010).

Children with language difficulties are served by NHS Speech and Language therapists and/or by schools' own provisions. However, services are stretched, particularly since the pandemic with recent work estimating that children are now, on average, educationally 3-4 months behind with the

poorest children worst hit (BBC news, 2020). Furthermore, schools and speech and language therapists have few rigorously tested interventions that they can use. The most recently available surveys of usual care (Dockrell et al., 2014, Lindsay et al., 2011) reported a 'proliferation of locally-developed programmes based on clinical experience' due to a lack of 'strongly evidence-based programmes', reflecting the paucity of research investment in this field (Bishop, 2010).

Rationale

E-PLAYS (Enhancing Pragmatic Language skills for Young children with Social communication impairment) is an intervention that has been developed and piloted by our team.

One of the most challenging situations for children with social communication difficulties is a context requiring collaboration, such as joint problem-solving or creative free play (Brinton et al., 2000; Kimhi et al., 2012, Murphy et al., 2014a, 2014b). E-PLAYS aims to facilitate and enhance children's interactions by providing socio-cognitive scaffolding within a fun, cooperative computer game. E-PLAYS supports communication based around naturalistic play with a peer and aims to embed learning in relevant contexts, thus promoting the *generalisation* of social skills.

An earlier version of E-PLAYS (known as the Maze Game, Murphy et al., 2014a, 2014b) was tested on 32 children. Children receiving the intervention showed significant improvement by comparison to a control group in pragmatic language test scores. A recent feasibility study of E-PLAYS (Murphy et al., 2021) with 50 children showed good response and completion rates, realistic recruitment and high acceptability by children and schools. These studies laid the groundwork for the present study which will conduct a randomised controlled trial of E-PLAYS on approximately 400 children to establish its effectiveness and cost-effectiveness definitively.

Care as Usual

The most recent surveys of usual care (Dockrell et al., 2014, Lindsay et al., 2011) reported a lack of available interventions for children with SCDs. These findings were borne out by interviews with schools and speech and language therapists in our previous study (Murphy et al., 2021). Activities typically included exercises on turn-taking, topic management, and conversational skills, sometimes with role-play or modelling. There is little evidence concerning the efficacy of these constituent activities (Lindsay et al., 2011; The Communication Trust).

The Intervention

The E-PLAYS programme is a computer game for two players on interlinked laptops. There are 10 weekly sessions, 30 minutes each; teaching assistants are trained to deliver and supervise all sessions. The game guides the child through real-life conversational exchanges with a specific focus on (a) requesting optimally useful information (b) giving helpful directions and (c) asking for clarification. Sessions with the classmate give the child an opportunity to practice these newly-acquired skills and also to learn collaboration skills through joint problem-solving with a peer. The E-PLAYS programme will be delivered by schools' teaching assistants with brief training and support from the research team. In our post-feasibility work, teaching assistants reported that they could follow the E-PLAYS manual with ease. We will therefore distribute E-PLAYS directly to schools and teaching assistants will largely self-train with the manual.

Research question

Does care as usual plus use of the E-PLAYS programme improve the language and communication skills of children aged 5-7 with social communication difficulties?

Aim

The aim of the E-PLAYS-2 trial is to establish the effectiveness and cost effectiveness of care as usual plus E-PLAYS programme which is designed to improve pragmatic language skills in children with social communication difficulties delivered in primary schools, compared to care as usual.

Trial Objectives

Objectives of the E-PLAYS-2 trial are:

1. To conduct an internal pilot to assess school recruitment, participant recruitment, fidelity to the intervention and data collection rates at 15-20 weeks post-randomisation with clear stop/go criteria;
2. Establish the effectiveness of the intervention on focal children (i.e., children with social communication impairments) using measures of pragmatic language skills at 40-week follow-up
3. Investigate the impact of the intervention on the pragmatic language skills of a randomly selected subset of (partner) children who do not have social communication difficulties
4. To undertake a full economic evaluation of E-PLAYS relative to usual care based on resource use of children and parents (from NHS, social care and education) and quality of life;
5. Conduct a process evaluation to examine intervention acceptability, delivery and fidelity.

Trial Design

Overview

The E-PLAYS-2 trial is a multi-centre, two-arm cluster randomised controlled trial with an internal pilot.

The E-PLAYS programme is designed to support children with social communication difficulties. E-PLAYS is built around a computer game played by two players; one child with social communication difficulties referred to throughout as the 'focal' child, and the 'partner' child without such difficulties. The programme comprises 10 weekly sessions lasting 30 minutes each with each session supervised by a teaching assistant who has been trained to deliver the intervention. Five sessions take place with the focal and partner child, five sessions take place with the focal child and the teaching assistant only.

The trial will take place in state-funded mainstream primary schools and state-funded special primary schools in the UK. Children aged 5-7 years old will be recruited to participate in the trial via their school that has chosen to take part in the trial. Potential participants will be identified by their Year 1 or Year 2 teachers using the Social Communication Behaviour Checklist (Adams et al., 2012) after which consent for their participation will be gained from their parent/carer. A teaching assistant from the school will be trained to deliver the intervention. We are expecting around 1.5

teaching assistants per class, therefore, should the initial teaching assistant become unavailable through sickness or other absence, we will recruit a replacement from the same school.

Randomisation will be at the school-level. Children in schools randomly allocated to the intervention group will receive 'care as usual' plus the E-PLAYS intervention. 'Care as usual' is defined as the existing support routinely provided for a child with social communication difficulties from educational services. Children in schools randomly allocated to the control group will receive 'care as usual' only. Control group schools will be offered E-PLAYS free of charge and they can use this as they wish after they have completed all post-tests.

The trial included a 12-month internal pilot phase. Initially we planned to recruit 25 schools and 150 focal children as part of this pilot (see Figure 1). If the progression criteria were met (see Section 'Internal Pilot – as planned'), the trial was expected to continue for a further year with the aim of recruiting an additional 59 schools and approximately 354 focal children. Hence, the plan was to recruit a total of 84 schools and approximately 504 focal children across the whole trial (both internal pilot and main trial). Detailed justification for this target sample size is provided in Sample Size Calculations – Original.

Recruitment of schools and participants to the internal pilot was completed in January 2023. A total of 20 schools and 91 focal children were recruited. The average number of participants per school cluster observed in the internal pilot was 4.55, around 25% smaller than the mean cluster size of six anticipated as part of the original research proposal. Following discussion with the funder, it was agreed that the trial would aim to recruit a total of 88 school clusters (20 pilot schools and 68 main trial schools). Further details and justification for these figures is provided in Sample Size Calculations - Revised.

All outcome measures will be completed for the focal children at baseline, post-test at 15-20 weeks post randomisation and follow-up at 35-40 weeks post-randomisation. Only data collected from the focal children will be used for the primary and secondary analyses regarding the effectiveness of E-PLAYS in the target population.

We also plan to undertake an exploratory analysis to assess the possible impact of E-PLAYS on partner children. For this, 88 partner children (1 from each participating school) will be selected at random to complete the TPS at baseline, post-test and follow-up, with these responses being used for the exploratory analysis.

The trial will also include a process evaluation (with focus groups, interviews and a survey) and analysis of the cost-effectiveness of E-PLAYS (see Figures 1 & 2).

Figure 1: Flow diagram of the E-PLAYS-2 internal pilot trial (as planned)

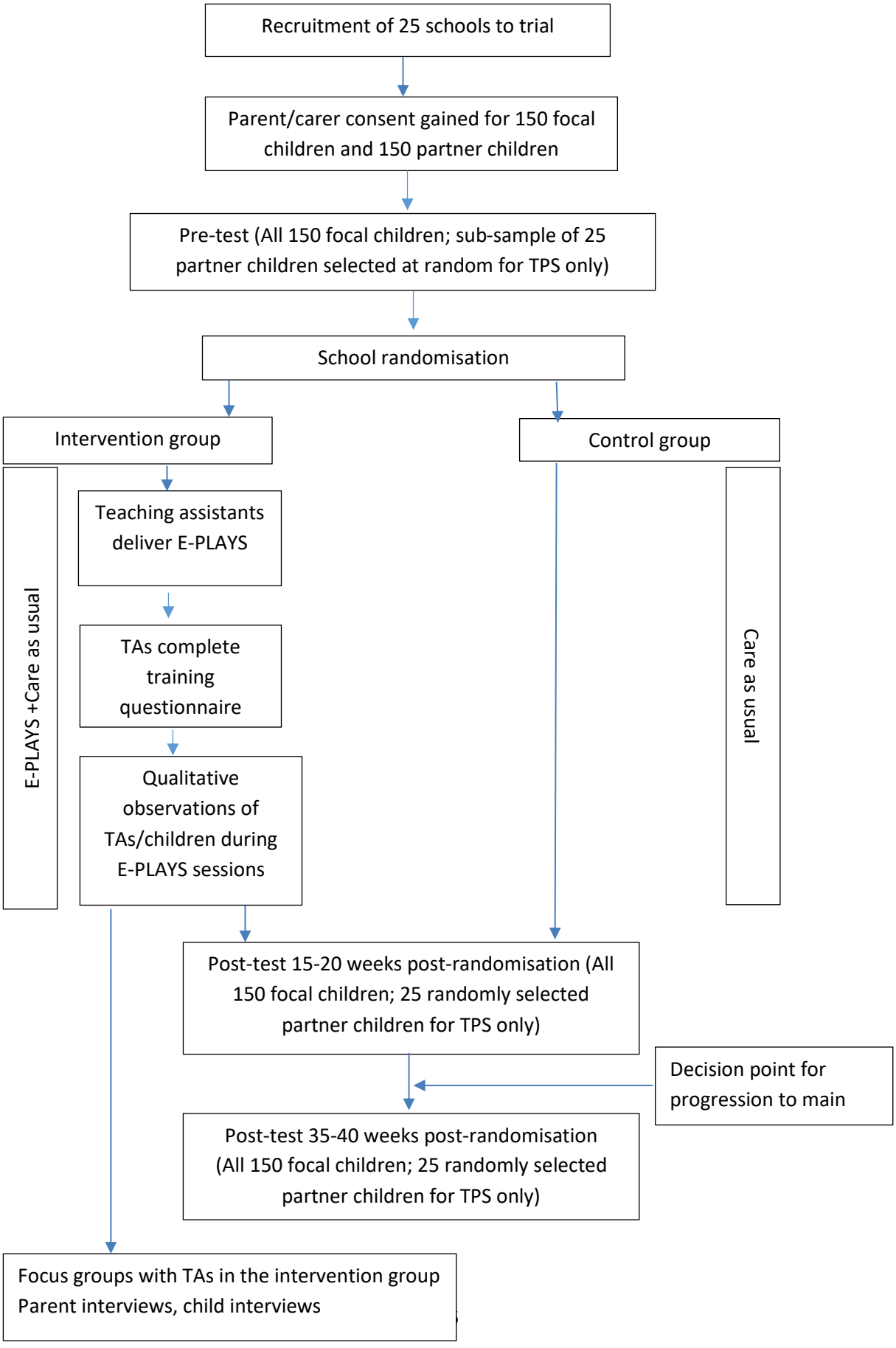
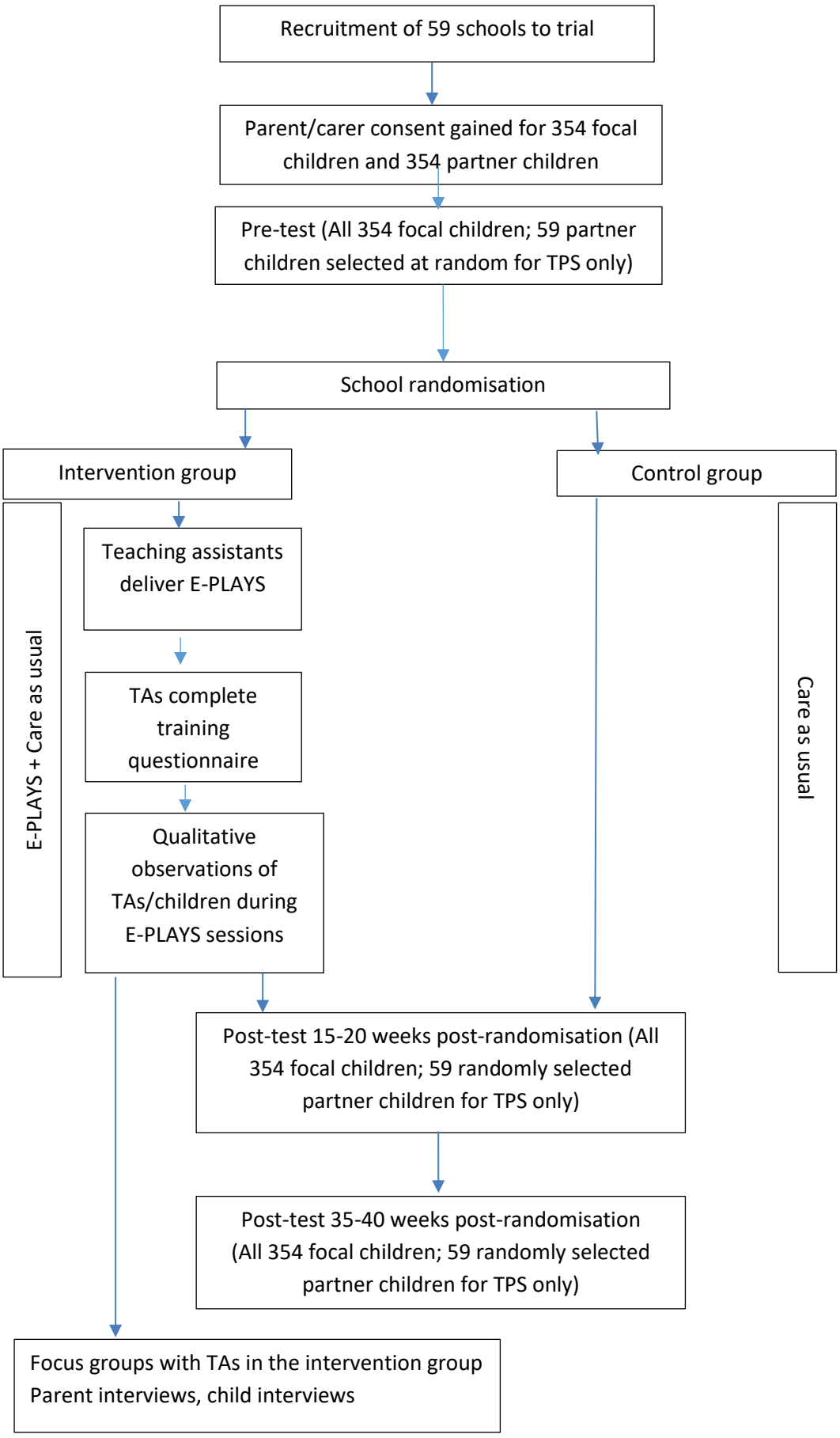


Figure 2: Flow diagram of the E-PLAYS-2 main trial (as planned)



Internal Pilot -

Months 13- 28 (September 2022 – December 2023) of the trial will constitute the internal pilot phase. During this time, we will aim to recruit 25 schools and approximately 150 focal children (average 6 per school) and 150 partner children. After receipt of the 15-20 weeks data, the trial team will report to the trial steering committee. Progress will be assessed and a recommendation made: (a) for the trial to continue to the main phase without major amendments or (b) continue with amendments to improve recruitment, retention and/or intervention adherence, or (c) to cease. We propose a traffic-light system (Avery et al., 2017) for the progression criteria:

Recruitment:

- Green ≥Recruit 80% of pilot school recruitment target and obtain engagement* from 80% of the number of remaining schools needed for the main phase of the trial (*defined as 'expression of interest form completed & submitted').
- Amber = 50-79%;
- Red = <50%.

Completion of the TPS at 15-20 weeks:

- Green ≥ 80%;
- Amber = 50-79%;
- Red = <50%.

Intervention completion and fidelity:

- Green ≥ 80% of intervention children complete at least 70% of E-PLAYS sessions;
- Amber = 50-79%;
- Red = <50%.

We will discuss strategies needed to progress to the main trial pre-testing phase with the Trial Steering Committee (TSC) and with NIHR if any of the targets are amber or red. We will also review the qualitative work conducted to reassess acceptability to children, schools and parents and discuss with our advisory group and TSC.
The internal pilot will be reviewed at the end of Project Month 23 (July 2023). Prior to this, an informal review will be requested by NIHR in Project Month 19 (April 2023).

Main Trial

The main trial will proceed assuming the internal pilot meets agreed progression criteria.

Randomisation

Randomisation will be completed by a trial statistician at York Trials Unit, who is not involved in school recruitment. They will randomise schools to either:

(1) The intervention arm which involves care as usual plus the E-PLAYS intervention or;
(2) The control arm which includes care as usual only.

Participating schools will be randomised 1:1 using minimisation to ensure balance across the trial arms on geographical location and the proportion of children in the school with free school meals (FSM; a proxy for deprivation). Proportion of children with FSM will be dichotomised at the median value observed for the internal pilot schools. A dedicated computer program, MinimPY (Saghaei and Saghaei, 2011), will be used for randomisation. The trial statistician will not be blind to group allocation.

Schools will be randomised in batches, once all baseline measures from the children collected by research assistants are completed in the school, to avoid predictability, maintain allocation concealment and prevent selection bias. Once randomisation is complete and a school has been allocated a trial arm, a member of the trial team will inform the school of their status by phone or email. The allocation will also be communicated to parents by the school.

Participants

Schools

The trial will recruit a total of 88 primary schools located in the South East and East of England.

School eligibility

Schools are eligible for participation in the trial if they meet the following inclusion criteria:

- Are a state-funded infant or primary school or special needs school
- Schools who have computer facilities (two available laptops) for children to use
- Agree to all requirements outlined in the E-PLAYS-2 Memorandum of Understanding and Data Sharing Agreement.

School exclusion criteria are:

- Independent, fee-paying schools
- Schools who are taking part in other language and communication research/trials aimed at pupils in Year 1 and Year 2
- Schools who have previously used E-PLAYS
- Schools who took part in the E-PLAYS feasibility study.

School recruitment

The research team at the University of Bedfordshire will lead on the recruitment of schools. Planned recruitment strategies include directly emailing schools who are based in the target recruitment areas, use of social media channels, promotion via public relations work, and working with contacts in relevant local authorities and providing them with recruitment materials to facilitate recruitment at a local level.

During initial contact, schools will be provided with information about the trial via email and asked to contact the research team if they would like further information. Following the initial email information, the research team will telephone the school to ensure the email has been received and gauge interest in participation, where possible. Where schools express an interest in participating, a member of the research team will arrange a convenient time to discuss the trial, in school or over the telephone, with an appropriate member of the school (e.g. a Head Teacher or a Special

Educational Needs Co-ordinator (SENCO)). Here they will share further information about the trial. Schools wishing to proceed with participation will be required to sign a Memorandum of Understanding (MOU) agreeing to the expectations of the trial, and a Data Sharing Agreement (DSA) between the school and the research team. This will clearly outline the requirements of the school at each stage of the study as well as the tasks to be completed by the trial team in conjunction with the school, such as training and process evaluation visits. We will collect data on the TAs within schools concerning which classes/year groups they are associated with at baseline.

The NIHR Clinical Research Network (CRN) will make direct payments to participating schools to facilitate trial set-up and child recruitment.

School retention and withdrawal

The research team will actively maintain contact with all schools throughout the trial and will work closely with their school contact to troubleshoot. The internal pilot will help to identify any issues with school retention or other early trial problems. Schools will receive a payment in Amazon vouchers as a thank you for taking part in the trial which should act as an incentive to continue participation and reduce attrition. The University of Bedfordshire will give the school one voucher after the baseline (pre-test) assessments are complete and another voucher at the end of the trial once the final assessments have been completed.

Where a school indicates that they wish to withdraw from the trial this will result in the full withdrawal of all participants and staff at this school. No further data will be collected. The school will inform the parents/ carers that they have withdrawn.

Child participants

The trial aims to recruit a total of 800 children, of which 400 are 'focal' children, and 400 'partner' children. Children who would be eligible to take part will be identified by teachers using the Social Communication Behaviour Checklist (Adams et al., 2012) which comprises a short 5-item questionnaire to confirm or reject their selection for focal children. Similarly, teachers will use the Social Communication Behaviour Checklist to confirm the selected 'partner' children do *not* meet the criteria for social communication difficulties. Child recruitment will take place prior to school randomisation.

Child eligibility

Focal children

Focal child eligibility criteria are as follows:

- Children aged 5-7 years old;
- Children who meet the criteria for social communication difficulties as determined by the Social Communication Behaviour Checklist (Adams et al., 2012) completed by the child's class teacher
- Children whose parents/carers provide consent for them to take part in the E-PLAYS-2 trial;
- Children who complete the research assistant administered baseline assessments
- Children who have not used E-PLAYS before

- Child's parent/carer willing to complete relevant questionnaires.

All focal children will complete all assessments listed below. Focal children's data will be used for calculation of the primary outcome.

Partner children

Partner child eligibility criteria are as follows:

- Children aged 5-7 years old;
- Children who do *not* meet the criteria for social communication difficulties as determined by the Social Communication Behaviour Checklist (Adams et al., 2012);
- Children whose parents/carers provide consent for them to take part in the E-PLAYS-2 trial.

Not all partner children will complete assessments. We will randomly select one partner child from each school to complete only the TPS at baseline and follow-up assessments. This will allow for a comparison of the outcomes in these typically-developing children between intervention (where the child will partner a participating child in E-PLAYS-2) and control schools (care as usual). Parents/carers of the partner children will be asked to consent to the partner child completing the TPS. One of the partner children will then be randomly selected to complete the TPS.

Child recruitment

Once teachers have identified the children eligible to take part in the trial, the teacher will distribute the paper information sheets and consent forms to their parents/carers. The participant information sheets will be supplied to schools by the research team, along with a simplified illustrated information sheet for children to read together with their parents/carers. The information sheets and consent forms will be relevant to whether the child is a focal child or partner child, and will be translated where needed. Included in the focal child's parent/carer information sheet will be details relating to the expectations of parents/carers to complete EQ-5D-Y, proxy version 1, CHU-9D, and resource use data questionnaires. All potential participants will be given the option to speak to a member of the research team or to contact the Chief Investigator in the event of additional questions.

Schools will be asked to send a reminder invitation pack to parents/carers if no response is received approximately 2 weeks after the original invitation pack was sent out. It is important to note that schools are limited to the number of children they can deliver the intervention to if allocated, as the delivery of the intervention is dependent on the availability of a teaching assistant(s) within the school. This will influence the number of eligible children schools invite to participate and gain consent for. With this in mind, schools will be asked to nominate at least one teaching assistant who will receive training and deliver E-PLAYS and schools will be asked to recruit at least 3 focal children. Schools with more teaching assistant capacity will be encouraged to recruit more children.

Child consent procedure

All potential participants will be given the option to speak to a member of the research team or to contact the Chief Investigator in the event of additional questions. Consent to enter the study will be

sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. The research team will provide parents/carers with two copies of the information sheet and consent form, one to complete and return to the school and the other to keep for their own records.

Participation in the trial will be entirely voluntary and written informed consent from parents/carers will be obtained before child baseline data is collected. On the consent form, parents/carers will be requested to consent for their child's school to provide the research team with data regarding their child, including name, date of birth, gender, year group/class, home postcode, ethnicity, religion/belief, English as an additional language (EAL), if the child has an Education, Health and Care Plan (EHCP) which will determine special education needs or disability (SEND) status, whether their child is under the care of a Speech and Language Therapist and/or Educational Psychologist and Free School Meal/Pupil Premium status (a proxy for deprivation). The consent form for parents/carers of focal children will also request parents/carers to provide their relationship to the child, highest educational qualifications, employment status, ethnicity and where applicable, the highest educational qualification and employment status of the 2nd caregiver. Additionally, consent/commitment will be requested to complete the EQ-5D-Y, proxy version 1, CHU-9D, and resource use data questionnaires at the specified time-points. Parents/carers should return completed consent forms to the school. The school will then return completed consent forms to the research team via a secure file transfer method (such as OneDrive). The school will be advised to securely store the completed paper consent forms until the research team's next visit to their school when they will collect the forms.

Child and parent/carer retention and withdrawal

Parents/carers of focal children will receive a shopping voucher to offset any incidental expenses associated with questionnaire completion at the end of the trial in recognition of their participation.

All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further care. The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act. If a child does not appear to want to take part at the time the E-PLAYS intervention is being delivered and/or assessments are taking place, their wishes will be respected. Where a child/parent/carer wishes to withdraw from the intervention, it will be clarified as to whether they wish to also withdraw from completing outcome measures, e.g. a child may be withdrawn from receiving the intervention and still provide outcome data, if willing.

Where a parent/carer wishes to withdraw from the trial, withdrawal will be clarified as to whether they wish their child to withdraw or if they themselves wish to withdraw (i.e. stop completing outcome measures). Where withdrawal is only for the participating parent, the child may continue to take part in all other aspects of the trial and follow-up data will continue to be collected where possible.

If a partner child withdraws before their school has been randomised, another child will be recruited to replace them. If the partner child that withdraws before randomisation has been randomly selected to complete the TPS, and they withdraw before the baseline assessment is complete, then

another partner child from that school will be randomly selected to complete the TPS. If a partner child in a school allocated to Intervention withdraws before the E-PLAYS sessions with their focal partner are complete, another child from the school will be recruited to replace them and take part in the remaining E-PLAYS sessions. If a partner child in a school allocated to Control withdraws, they will not be replaced. If a partner child withdraws post-randomisation and they were selected to complete the TPS, no other partner would be selected to complete TPS.

Teaching Assistant retention and withdrawal

Where withdrawal is only for the teaching assistant, we will ask schools to replace them for the intervention period. Where a teaching assistant cannot be replaced, the research team will discuss the implications of this with the school who will communicate with the affected participant(s) to establish if they wish to continue with providing outcome data.

Outcome Measures

Outcome measures will be provided by three different kinds of reporters: independent research assistants (RAs), parents/carers and teachers.

RAs will be blind to group allocations when collecting quantitative outcome measures listed below. They will have received relevant training from the research team. All RAs will have an enhanced Disclosure and Barring Service check and undergo relevant safeguarding and data protection training. For all assessments that are completed by an RA, we will advise schools that a familiar staff member should be available to chaperone the assessment conducted by the RA to ensure the child feels comfortable. When a research assistant visits a school to administer the assessments, teachers and teaching assistants at the schools will be reminded on every visit not to reveal allocations to the research assistants. Any instances of unblinding during the assessments will be recorded (using a bespoke unblinding form which will include information on who was unblinded, the source of unblinding, and the reason for unblinding) and the unblinded RA will be replaced with another RA who is blind. RAs will also collect qualitative data from schools, summarised in Table 3 and detailed further on p26, however, for this data, they will not be blinded.

Teachers and parents/carers will be requested to complete outcome measures for focal children. Whilst blinded during the completion of these outcome measures at baseline, they will not be blinded at 15-20 or 35-40 weeks post-tests.

Table 1 provides a summary of the objectives and all primary and secondary outcome measures.

Table 1. Objectives and outcome measures

Outcome	Objective	Outcome measure
Primary	Improve focal children's pragmatic language skills (35-40-weeks post-randomisation)	Test of Pragmatic Skills (**TPS**)
Secondary	Improve focal children's pragmatic language skills (15-20-weeks post-randomisation)	Test of Pragmatic Skills (**TPS**)
	Improve specific language skills i.e., recall and instructions	Recalling Sentences, Following Directions (**CELF-5** subscales), narrative recall (**ERRNI)**
	Enhance children's perspective-taking	**Droodles** task**,** Communication Test **(CT),** Director's Task **(DT)**
	Improve children's social behaviour, peer relations and mental health	Strengths and Difficulties Questionnaire (**SDQ**)
	Improve children's generalized communication skills	Children's Communication Checklist (**CCC-2**)
	Measure cost-effectiveness	Bespoke resource use questionnaire
	Improve quality of life	EuroQoL **(EQ-5D-Y** proxy version 1), Child Health Utility (**CHU-9D**)
	Improve partner children's (subset) pragmatic language skills	Test of Pragmatic Skills (**TPS**)

Primary Outcome

Pragmatic language: The primary outcome will be the Test of Pragmatic Skills (TPS, Shulman, 1986), administered by an RA at baseline, and at 15-20 and 35-40 weeks post randomisation, with the 35-40 week outcomes serving as the primary endpoint. Assessment results will be collected on audiotape and then entered electronically.

Secondary Outcomes

The following secondary outcome measures will be administered to focal children during school by an RA at baseline, 15-20 weeks and 35-40 weeks post-randomisation.

- **Specific language skills**: Clinical Evaluation of Language Fundamentals-5 (CELF-5; Wiig et al., 2013) - Recalling Sentences and Following Directions subscales. CELF-5 is a commonly used language and communication test in clinical settings.
- **Specific language skills**: Expression, Reception and Recall of Narrative Instrument (ERRNI; Bishop, 2004) assesses the ability to relate, comprehend and remember information after a short delay. The assessment presents children with a series of pictures and asks them to tell the story according to the pictures. There are two stories, 'The Beach' and 'The Fish'. Both stories are balanced, so that scores are similar on both. One story is used at baseline and the other at post-test. The stories will be counterbalanced, so that half the children are administered 'The Beach' at baseline, and the remaining children will be administered 'The Fish'. At the 15-20 post- randomisation follow-up, children will be administered the story

they have not yet completed. At the 35-40 weeks follow-up, children will repeat the story they were administered at baseline.

- **Perspective-taking skills**: Droodles Tasks and Communication Test (Carmiol & Vinden, 2013; Matthews et al., 2007; Miller et al., 2003), and Director's Task (Rubio-Fernández, 2016). These are a series of tasks and puzzles testing children's ability to evaluate the effects of ambiguous versus informative communications, a key skill targeted by E-PLAYS. The tests are embedded in play sessions with dolls and puppets and have previously been used for this age group.

The RA will administer the assessments in the following order. The TPS will be administered first as it is play-based and should help to relax the child, followed by CELF subscales Recalling Sentences and Following Directions, then Droodles, Communication Test and Director's task and finally ERNNI. Assessment delivery will be paused as and when is needed. The assessments detailed above will take approximately 45 minutes to administer per child at each data collection time-point. The children's tests are mostly tasks set within play routines so we have generally not found these onerous for the children. These tests can be divided into two or more sessions as the children are very young and may tire.

The following secondary outcome measures will be completed by focal children's parents/carers at baseline, 15-20 weeks and 35-40 weeks post-randomisation:

- **Health-related quality of life**:
    - Child Health Utility (CHU-9D), paediatric generic preference-based measure of quality of life. The CHU-9D includes specific dimensions on school and joining in with activities (Stevens, 2009, 2011).
    - EQ-5D-Y proxy version 1. This is a widely used standardised generic measure of health-related quality of life for younger children (Wille et al., 2010).
- **Resource use data:** A bespoke questionnaire (developed for the E-PLAYS feasibility study) will collect resource use data (Murphy et al., 2019) for health care, voluntary organisations and educational resources.

We anticipate that it will take parents/carers approximately 30 minutes to complete the questionnaires at each data collection time-point. Parents/carers will have the option of completing these questionnaires online, on paper or over the telephone with a research assistant. If the parent/carer wishes to complete the questionnaires on paper, the research team will request the school distribute these and ask the parent/carer to return them to the school once complete.

The following secondary outcome measures will be completed by focal children's teachers at baseline, 15-20 weeks and 35-40 weeks post-randomisation; these measures are completed by the teachers without the child needing to be present:

- **Children's communication impairment**: Children's Communication Checklist-2 (CCC-2, Bishop, 2003). CCC-2 is a standardised questionnaire of children's communication impairment.

- **Social behaviour, peer relations and mental health**: The Strengths and Difficulties Questionnaire (SDQ, Goodman, 2001). SDQ is widely used as a mental health indicator with subscales assessing behavioural, emotional and peer problems.

We anticipate the questionnaires detailed above will take the teacher no longer than 10 minutes per child to complete at each data collection time-point. Teachers will be requested to provide this data securely online, via a survey.

The following secondary outcome measures will be administered to a randomly selected subset of 88 partner children (1 per school) during school time by an RA at baseline, 15-20 weeks and 35- 40 weeks post-randomisation:

- **Pragmatic language**: Partner children's pragmatic language skills measured using the validated TPS (Shulman, 1986).

Table 2 summarises all outcome measures by reporter below.

Table 2: Summary of primary and secondary outcome measures by administrator

Outcome measure	Baseline assessments	15-20 weeks	35-40 weeks
Research Assistants			
TPS	X	X	X*
TPS (88 partner children only)	X	X	X
CELF-5 (Recalling Sentences and Following Directions)	X	X	X
ERRNI	X	X	X
Droodles, CT, DT	X	X	X
Parent/carer			
EQ-5D-Y	X	X	X
CHU-9D	X	X	X
Bespoke resource use questionnaire	X	X	X
Teacher			
CCC-2	X	X	X
SDQ	X	X	X

*Primary outcome

Table 3: Process evaluation data collection methods conducted by research team

	Data collection method	Consent	Pre-randomisation	Post-training, pre-intervention	During intervention	Post-intervention
		X				
Intervention group TAs	Training questionnaire			X		
	Focus groups					X
	Structured observations (Case schools)				X	
Control group TAs	Interviews				X	
Intervention and Control group TAs or SENCOs	Treatment as usual (TAU) Survey		X			X
Intervention group children	Structured observations				X	
	Structured interviews (Case schools)					X
	E-PLAYS software: duration & no. sessions				X	
Intervention group Parents	Interviews (Case schools)					X
Schools	School data		X			
	Training and experience (TAs)			X		
	Class/year association (TAs)		X			
	Recruitment log		X			

Statistics and Data Analysis

Sample Size Calculations – Original

We will recruit single- and multi-form entry schools. Pupils will be recruited from Years 1 and 2; assuming an average of 2 classes per year, we expect to identify a mean of 10 eligible children per school, of which 6 will consent and be recruited. The intervention will be delivered to the participating children by teaching assistants and we expect an average of 1.5 TAs per class.
In multi-form entry schools, we will have clustering of classes within year groups, but in one-form entry schools the levels of class and year will be equivalent. We consider that in multi-form entry schools the difference in clustering between class and year will be negligible so we shall ignore the level of class. Therefore, this cluster randomised trial assumes a three-level structure in that pupils (level 1) are nested within year group (level 2) nested within schools (level 3). Randomisation will

take place at school-level. The year groups participating in this trial are consecutive (Years 1 and 2) so the difference between them will be minimal and the cluster effect of school will likely dominate the effect of class; therefore, we have not explicitly accounted for clustering at the class level in this sample size calculation. The largest influence within schools is likely to be between TAs since these will be the ones delivering the intervention to the children; however, in most schools we expect that the ratio of TAs to participating children will be approximately 1:1 so this level of clustering is eliminated. In the feasibility trial, the school-level intraclass correlation coefficient (ICC) was small (<0.01); here we have assumed a conservative ICC of 0.05 at the school-level to account for all levels of potential clustering.

In our feasibility trial, the standard deviation (SD) of the primary outcome measure, the TPS (Shulman, 1986), at baseline was 7.2 (95% CI 5.4 to 9.7) and the observed correlations between the TPS score at baseline and the scores at weeks 15-20 and 35-40, respectively, were 0.84 (95% CI 0.71 to 0.91) and 0.79 (95% CI 0.63 to 0.89). In the calculation for this trial we assume: a SD of 7, an ICC of 0.05 at the school-level, a mean cluster size of 6 (focal children per school, at randomisation), 20% pupil level attrition at follow-up and a more conservative pre-post correlation of 0.6. To detect a difference in TPS score of 2 points (a third of a year's progress based on the standardisation sample given in the TPS manual), with 90% power and a two-sided alpha of 5%, we would require 84 schools (504 focal children).

We plan an exploratory analysis to assess the potential impact of the intervention on partner children's (those who do not have social communication difficulties) social pragmatic language skills. We will randomly select one potential partner child from each school to complete the TPS at baseline, post-test at 15-20 weeks post-randomisation and at follow-up at 35- 40 weeks post-randomisation with a blinded, independent research assistant. This will allow for a comparison of the outcomes in these typically-developing children between intervention (where the child will partner a participating child in E-PLAYS) and control schools (care as usual).

Since this is an exploratory analysis, we have planned the sample size of one typically-developing child from each school for logistical reasons. Collecting the TPS from only one extra child per school will not substantially increase the time or burden to complete outcome measures. A sample size of 84 children, assuming a SD of 7, a pre- post-test correlation of 0.6 and 20% attrition, will give 80% power to detect a difference of 3.9 points in the TPS.

Sample Size Calculations - Revised

For the 20 school clusters recruited as part of the internal pilot phase, the observed mean cluster size (at randomisation) was 4.55 participants per cluster, around 25% less than the anticipated 6 participants per cluster detailed in the previous section. Assuming a mean cluster size (at randomisation) of 4.55 and keeping all other assumptions the same as previously (e.g.δ = 2, SD = 7, pre-post correlation = 0.6, school level intra-cluster correlation of 0.05 and 20% participant level attrition), the planned 42 clusters per group would provide approximately 83.5% power for a two sided test of $H_0: \delta = 0$ (where δ is the difference in expected TPS score at 35-40 weeks)

Following discussion with the funder the total target number of school clusters was changed to 88. Assuming a mean cluster size (at randomisation) of 4.55 and keeping all other assumptions the same

as previously (e.g.δ = 2, SD = 7, pre-post correlation = 0.6, school level intra-cluster correlation of 0.05 and 20% participant level attrition), 44 clusters per group would provide approximately 85.2% power for a two sided test of H_0: $\delta = 0$ (where δ is the difference in expected TPS score at 35-40 weeks).

Statistical analysis plan

Statistical analysis will be conducted in Stata v17 or later, using two-sided tests at the 5% significance level under the principles of intention-to-treat, including all schools and pupils in the group to which they were originally allocated. Reporting will be in accordance with CONSORT guidance for cluster RCTs.

Summary of baseline data and flow of participants

The number of schools and children screened, consenting and randomised will be summarised. Reasons for non-participation will be provided where available. The flow of schools and participants will be presented in a CONSORT flow diagram. School and pupil baseline data will be summarised descriptively by group, as randomised and for those included in the primary outcome analysis. No formal statistical comparisons will be undertaken. Continuous measures will be reported as means and SD, while the categorical data will be reported as counts and percentages.

Primary outcome analysis

The primary analysis will compare participant level TPS scores between the groups using a covariance pattern linear mixed effect model, incorporating both post-randomisation time points as outcomes. The model will adjust for baseline TPS score, year group (1 or 2), geographical location of the school, child FSM status, time point, treatment, treatment-by-time point interaction as fixed effects. Dependence between outcomes within the same school will be modelled using school level random intercepts and dependence between repeated measurements within participant will be modelled using an unstructured covariance matrix for the residual errors. The estimated treatment effect at both time points will be obtained from the fitted model in the form of an adjusted mean difference together with appropriate95% confidence intervals and p-values.

Secondary outcome analysis

Continuous secondary outcomes will be analysed similarly to the primary outcome.

Further analyses of the primary outcome

A complier average causal effect (CACE) analysis for the primary outcome will be considered to estimate the effect of the intervention among children with SCD that would receive E-PLAYS if and only if they were offered it (i.e. the average causal effect of treatment in the complier principal stratum)..

The primary analysis will condition on random intercepts for school to account for clustering of outcomes by school. In sensitivity analyses, we will explore the potential impact of clustering at other nested levels. We will consider a series of models that include:

- A random effect for year nested within school;

- Random effects for class nested within year nested within school (note, in single-form entry schools, class and year will be equivalent, so if this model does not converge we will omit the random effect for year).
- A random effect for TA nested within school (if TAs are also nested within class and/or year groups then these levels will be considered as random effects in this model too).

We will also conduct a sensitivity analysis for the primary outcome in which the primary analysis model is augmented with additional covariates for child EAL, SEND and EHCP status.

Procedure(s) to account for missing or spurious data

The amount of missing data will be reported by trial arm. A comparison of the baseline characteristics of schools and pupils who are included in the primary analysis will be undertaken to investigate whether attrition has resulted in any imbalance in the groups with respect to important baseline covariates. Logistic regression will be used to identify baseline variables associated with missing primary outcome data at 15-20 and/or 35-40 weeks. The primary analysis will then be repeated, including as covariates all variables found to be associated with missing primary outcome data. Additional imputed data analyses to further relax the assumption that the missing primary outcome data are missing at random (MAR), and investigate the sensitivity of the results of the primary analysis to various systematic departures from MAR will be undertaken if greater than 10% of randomised schools or participants are not included in the primary analysis.

Process Evaluation

A mixed-methods process evaluation, following MRC recommendations for RCTs (Moore et al., 2015), will assess E-PLAYS' acceptability and fidelity of implementation, mechanism of impact, and examine contextual influences on implementation and outcomes. This evaluation will use quantitative and qualitative data across the entire school sample alongside observation, interview and focus group data from four purposively-selected case study schools. Research assistants (trained by the research team) will conduct the interviews, observations and focus groups described below.

Schools

Surveys will be delivered via online survey software, with a paper version available on request.

Teaching assistants

Teaching assistants will be requested to complete an online open-ended questionnaire to gauge satisfaction with training and manual immediately post-training (intervention group). We will conduct focus groups with teaching assistants at the end of intervention to explore views on E-PLAYS-2, delivery and participation in study (intervention group only). One focus group will be conducted per school to which all the participating teaching assistants from that school will be invited. We will randomly select 4-6 schools from those in the internal pilot and 4-6 from those in the main trial for the focus groups, or until saturation.

Similarly, we will explore via focus groups (one per school, 4 in total or until saturation), the impacts of deprivation and English as an additional language with the case study schools.

We will also conduct a survey of all teaching assistants. For those in the intervention group this will provide us with a wider sample of views than those from the focus groups above; for those in the control group this will give us insights into usual care. We will also include 6-8 structured interviews with a subset of the control group teaching assistants to further explore the usual care provided. Written consent will be obtained from teaching assistants to participate in focus groups and interviews. We will also collect baseline information on TAs' training and experience.

Participating children

We will carry out structured observations of 40 pairs of focal children plus their partners to assess enjoyment and learning. This will be a purposive sample to reflect varying language ability levels (i.e., pragmatic language scores at baseline, English as a second language). Importantly, the reactions of the partner children to the focal children will be observed to see whether these are positive or negative. The relationship between the focal child and the partner child is an important element of the E-PLAYS intervention.

Participating parents

To examine potential spill-over effects into family life, a sub-set of individual structured interviews with parents (n=20) will be conducted across the four case study sites at 15-20 weeks post-randomisation. We will also explore the extent to which children played computer games at home before and after the intervention and any changes to game-playing. We will collect post-test information from the same parents of the time that children play games at home to see if using E-PLAYS influences this behaviour. Interviews will take around 30 minutes and will be conducted in schools.

Case study schools

Four intervention schools will be purposively sampled to act as case studies (Yin, 2018). Schools will be profiled to include at least the following; one special needs school and one mainstream school plus one school with high levels of deprivation and another school with a high proportion of children with English as a second language. These schools will be approached to be case studies *before* the E-PLAYS intervention is given to them and will continue to be observed throughout intervention delivery. The following assessments will take place:

- One structured interview with (n=20, five from each school) focal children and their partner (n=20, five from each school) children with a card sorting task and visual analogues to give an indication of their liking of E-PLAYS;
- Structured observations of teaching assistants delivering E-PLAYS sessions (n=20, five from each school) will assess teaching assistants' fidelity to the manual instructions using a checklist developed during our feasibility trial (Murphy et al., 2021).

Monitoring data: E-PLAYS-2 software will record the content, duration and number of intervention sessions each child receives using a unique login ID. This monitoring data will be summarised as part of the process evaluation, and also incorporated into a CACE analysis if/where appropriate.

Process evaluation analyses

Qualitative data will be (with written consent) audio-recorded, transcribed verbatim and managed using NVivo11 software. A six-step reflexive realist thematic analysis approach (Braun & Clarke, 2019) will be used to report the experiences, meanings, and reality of participants. Two experienced qualitative researchers will independently code a subsample of transcripts where initial codes will be compared, discussed, and agreed on prior to coding on all other interviews. Codes will be generated both from the topics in the interview guides and iteratively from the data to attain both the facilitators and challenges of the intervention. Interim themes will then be discussed, refined, and agreed by two researchers and the research team. Detailed analysis of each theme will be presented with illustrative anonymised quotes used to typify the data. Individual interview and focus group data will be analysed separately alongside together to identify and map overarching themes related to experiences of the intervention. Comparative analysis across the case study schools will also be conducted to explore the impact of the intervention and examine experiences across different school contexts.

Economic evaluation

The costing approach will be undertaken primarily from the perspective of the National Health Service (NHS) but will also consider the perspective of both Social and Education Services.

The economic evaluation will assess the cost-effectiveness of E-PLAYS compared with usual care. Individual participant data from the trial will be used to evaluate resource use, costs, health and social outcomes associated with the intervention and will be collected over the follow-up period of the trial.

The primary economic outcome will be the difference in costs and the difference in quality-adjusted life year gained by receiving E-PLAYS using an intention-to-treat approach. Costs and outcome data for the economic analysis will be collected prospectively during the trial using proxy-reported questionnaires at baseline and at each follow-up.

The primary analysis will be conducted using the CHU-9D which is a paediatric generic preference-based measure of quality of life that includes specific dimensions on school and joining in with activities, and allows for the calculation of QALYs (Stevens et al., 2011). To ensure comparability with similar interventions, a secondary analysis will be conducted using the EQ-5D-Y (Wille et al., 2010). Both instruments will be collected from proxies at baseline and at each follow-up. Mean within-trial costs and benefits will be calculated using regression methods adjusting for baseline covariates as well as any correlation between costs and utility. Multiple imputation methods will be used to deal with missing data if appropriate. Uncertainty will be described using confidence intervals and cost-effectiveness acceptability curves (CEACs). A range of sensitivity analyses will be conducted to test the robustness of the results under different scenarios.
The bespoke resource use questionnaire developed for the feasibility trial of E-PLAYS will be used. Health care resource use will be presented for both arms in terms of mean value, standard deviation and mean difference (with 95% CI) between the groups. The cost of the intervention will be estimated according to treatment and resource use costs. Treatment costs will include such as staff, equipment and software costs. Unit costs will be derived from established national costing sources

such as NHS Reference Costs and PSSRU Unit costs of health and social care. Unit costs will be multiplied by resource use to obtain a total cost for each patient.
The cost of delivering E-PLAYS was estimated in the feasibility trial. To confirm this, a costing exercise will be undertaken taking a bottom-up approach to identify and place a value on the constituent parts of the intervention delivery, e.g. staff and training costs, to estimate its total cost in monetary terms and in terms of the time required including that of existing school staff.

The results of the trial will provide an estimate of the relative effect of E-PLAYS compared with usual care for the time horizon of the trial. However, there is potential for the impact of the intervention to extend far beyond what is measurable during a trial, for instance into long-term educational outcomes and future criminal activity/anti-social behaviour. We will conduct a systematic review to identify any existing models that link the shorter-term outcomes of the trial, for example behavioural problems as measured by the SDQ, to longer term outcomes. One potential such model would be the Dartington model (Little et al., 2013) which could be used as the basis for linking short term outcomes to longer term educational attainment, future criminal activity and labour market productivity, though there are possibly other models available. We will use any identified models to examine the likely additional costs and benefits of the intervention over the longer term. As with the within-trial analysis, health and educational effects will be presented separately and the potential values of the outcomes will be explored for both sectors. A discount rate of 3.5% will be applied for costs and outcomes.

Data Management

Data collection tools and source document identification

Data collected as part of this trial includes assessments, questionnaires and qualitative data from interviews, surveys, and structured observations. Data from teachers will be collected electronically. Data from parents will be collected through electronic surveys or paper questionnaires designed by the research team and entered into an anonymised database. RAs will collect data via audio recording, paper and electronically from children. Anonymised data will be sent to the YTU statistician to be error checked and validation checks will be run against the data base, for example to identify any implausible values. Discrepancies identified during validation which require resolution will be raised as data queries to the relevant person. They will then attempt to obtain the information required to rectify the discrepancy. If the discrepancy cannot be rectified an assumption may be made at the point of analysis by the trial statistician. Any assumptions will be documented. All data queries raised, and resolutions, will be fully documented.

Every attempt will be made to ensure the data is accurate, complete and reliable.

- If data are found to be missing from participant completed questionnaires, participants will be contacted by a RA in an attempt to collect the data, where appropriate.
- Validation reports will be run regularly by YTU to check the study data for completeness, accuracy and consistency. Discrepancies will be generated and managed to resolution.
- Participants (parents/carers, school staff) will be contacted by email or phone (approximately two weeks after follow-up is due) asking them to complete questionnaires.
- All interviews and focus groups will be transcribed verbatim by a transcription service who use standard confidentiality agreements that cover UK GDPR requirements.

Data handling and record keeping

Where relevant, trial data will be extracted from source documents/recordings and entered onto the trial database.

All information collected during the course of the study will be kept strictly confidential. All identifiable participant data will be coded, pseudonymised by participant number in all manual and electronic files. Output for analysis will be generated in a format, and at intervals, to be agreed between YTU and the CI. Data will be stored on University computers; these will all be password-protected. Data from qualitative interviews will be transferred onto the secure server as soon as possible and data removed from the portable, secure, encrypted recording device as soon as possible.
All data will be collected and retained in accordance with the UK General Data Protection Regulation, Data Protection Act 2018 and YTU SOPs. The University of Bedfordshire and the University of York are deemed joint data controllers for the trial. The study consent form will include optional statements affirming agreement with sharing anonymised data and affirming agreement to being contacted about future research.

The sponsor will permit monitoring and audits by the relevant authorities. The Chief Investigator will also allow monitoring and audits by these bodies and the sponsor, providing direct access to source data and documents, including the database. The YTU data management system incorporates quality control to validate study data.

Access to Data

The final anonymised trial dataset will be available to all trial team members/investigators if a formal request describing their plans is approved by the Trial Management Group. To ensure confidentiality, data dispersed to trial team members will be blinded of any identifying participant information. Appropriate anonymised datasets will be provided to the chosen public repository, such as the UK Data Archive, for archiving.

Archiving

Anonymised data will be made available from the end of the trial. This will include individual anonymised participant data and study publications including the study protocol, statistical analysis plan, health economics plan, and case report forms. Data from this study will be available via a sponsor-controlled application process for which applicants must show that they have sound scientific reasons for accessing the data and acceptable research methods. Consent for the sharing of *anonymised* data will be obtained from all study participants. At the culmination of the study, we plan to apply to share our anonymised data in a public repository such as the UK Data Archive where it would be accessible to other researchers. In order to enable this, we will highlight on our Participant Information Sheets and consent forms that anonymised data may be shared in this way.

Ethics and Regulatory Considerations

- Ethical approval for the trial has been sought from University of Bedfordshire, Institute for Health Research Ethics Committee. Approval via Chair's Action will be sought from The University of York's Health Sciences Research Governance Committee.

- The proposed study will be conducted in accordance with ICH Good Clinical Practice guidelines.
- Data Protection Impact Assessments will be developed and approved by both the University of Bedfordshire's and the University of York's data protection teams.
- A Memorandum of Understanding signed by schools will cover the requirements of the trial.
- Data Sharing Agreements (DSAs) will be put in place between the University of Bedfordshire and each participating school.
- A DSA will cover data sharing requirements between the University of Bedfordshire and the University of York.

Ethical amendments and reporting

Any necessary non-substantial amendments will be approved by the CI. Substantial amendments will be reported to NIHR in the first instance, no actions will be taken until approval from NIHR is received. Additionally, amendments that require review by ethics committee will not be implemented until the ethics committee grants a favourable opinion. All correspondence with the ethics committee and NIHR will be retained in the Trial Master File (TMF). Amendment history will be tracked by adopting version control and by the use of an amendment log. Any changes relevant to schools will be communicated in writing at the earliest opportunity following approval.

Trial Monitoring

The trial is sponsored by University of Bedfordshire.

Trial monitoring procedures and site monitoring will be undertaken at a level appropriate to a risk assessment performed by the Sponsor. YTU Standard Operating Procedures (SOPs) will be followed where applicable and the research team will be trained as appropriate. Significant findings will be presented to the appropriate oversight committee.

Trial Management Group

The Trial Management Group (TMG) will be the decision-making body who will be responsible for the day-to-day running and management of the trial. The TMG will comprise the Chief Investigator, the co-applicants, the trial manager and other key members of the research team. The Trial Management Group will meet at least monthly.

Trial Steering Committee

A Trial Steering Committee (TSC) will be established to govern the conduct of this study. This committee will function in accordance with YTU SOPs. The TSC will be led by an independent chair, a senior academic in the field of the research, and will comprise 75% independent members (as per NIHR's definition https://www.nihr.ac.uk/documents/research-governance-guidelines/12154).
The TSC will meet approximately every 6 months from the start of the trial.

Advisory Group (Public and Patient Involvement)

An advisory group will input into the trial and advise on matters such as recruiting a diverse sample, producing an accessible Participant Information Sheet and other relevant participant-facing study

documents, support for teaching assistants and dissemination of our findings to participants and the general public. The advisory group will comprise a mix of parents of children with SCD, teachers, speech and language therapists and relevant charity representatives. All members from the advisory group will be supported by a dedicated research team member. They will plan activities such as the preparation of information sheets and newsletters and other promotion of E-PLAYS. The dedicated research team member will also provide feedback on these activities and their impact and will plan activities to distribute and promote E-PLAYS nationally if it is found to be effective at the end of the study.

Complaints

Schools and parents/carers will be provided with the CI contact details and contact details of the Director of the Institute for Health Research at the University of Bedfordshire should they wish to make a complaint about the conduct of the trial. Complaints will be dealt with by the CI, who will liaise with the Sponsor (University of Bedfordshire) and the wider research team will be informed.

Indemnity

To meet the potential legal liability for harm to participants arising from the design, conduct and management of the research, university employees will be covered by their institution's insurance. E-PLAYS intervention sessions will be held on school premises, therefore trial participants and all education professionals involved will be covered by the school's indemnity insurance. The University of Bedfordshire will obtain and hold public liability insurance cover for legal liabilities arising from the trial.

Protocol compliance and breaches

Accidental protocol deviations will be documented on the relevant forms and reported to the CI immediately.

Financial and other competing interests

Competing interests that might influence trial design, conduct or reporting will be declared. There are currently no competing interests. This includes ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial. E-PLAYS was designed by the Chief Investigator. It is not anticipated that there will be any commercial value, however, the foreground intellectual property remains the property of the University of Bedfordshire. The Trial Steering Committee will determine any other matters that it is appropriate to report.

Adverse Events and Safeguarding

Serious Adverse Events (SAEs) and Adverse Events (AEs)

Due to the nature of participant involvement no serious adverse events or adverse events that are unexpected and related are anticipated. However, the study team will monitor adverse events throughout the study.

Expected Events

This is a low-risk study and the trial team has not identified any adverse events that are expected and that could be related to the intervention or to taking part in the study so this will be determined on a case by case basis by the Chief Investigator. It is expected that there may be unrelated incidents of hospitalisations, illnesses, disabling/incapacitating/life-threatening conditions, other common illnesses and rarely deaths in the study population. We will not seek to record all such events. We only seek to record those that could be related and are unexpected.

Related Events

An event is defined as 'related' if the event was possibly, probably or definitely due to the administration of any research procedure. The relatedness of an event will be reviewed by the Chief Investigator and the Trial Steering Committee. An 'unexpected event' is defined as a type of event not listed in the protocol as an expected occurrence.

Reporting of adverse events

A researcher from the University of Bedfordshire will periodically check-in with schools to collect information about any adverse events or untoward occurrences regarding participation in E-PLAYS-2 during the intervention period. Details of any SAEs or AEs that *come to the attention of* the research team, including those reported to the study team by participating children, their parent/carer or school staff, and those identified by the researcher during child assessments, child observations and child and parent/carer interviews, will be considered by the Chief Investigator and the trial team.

SAEs/AEs that are considered by the CI as related and unexpected, will be recorded using a trial adverse event form.

If the event is an SAE, the CI will decide if the event should be reported to the ethics committee as an SAE (i.e. unexpected and related). In the case of an SAE which is related/unexpected the CI will report to the: Sponsor immediately upon knowledge or as soon as practically possibly; TSC immediately; University of Bedfordshire's Institute for Health Research Ethics Committee within 15 days; TMG at the next scheduled meeting; to the funder during regular progress reports.

In the case of an AE which is unexpected and related the CI will report to the Sponsor immediately or as soon as is practically possible and to the TSC/TMG at the next scheduled meeting.

If the SAE/AE is not unexpected and related it will be recorded and reported to the Sponsor immediately upon knowledge of the event or as soon as is practicably possible to do so, and the TSC and TMG at the next scheduled meetings.

The AE/SAE reporting period for E-PLAYS-2 begins when the first baseline data are collected for the participant (completed by the teacher, the parent/carer or the research assistant) and ends when the final data are collected for the participant at 40 weeks post randomisation, or earlier if the participant fully withdraws before that point.

At the University of Bedfordshire, only the CI will have access to the SAE/AE log, and completed SAE/AE forms (e.g. folder on secure server) as to not unblind other members of the research team. Relevant documentation will be securely transferred to University of York for reporting purposes.

Child safeguarding issue

In the very rare circumstance that a child safeguarding issue is suspected, for example during data collection, a Study Specific Procedure will be followed. Here the research staff member should immediately inform the school's Designated Safeguarding Lead, or in their absence, the Deputy DSL, or most senior member of staff available, and complete the schools' Safeguarding Concerns Reporting Form if request to do so. The CI should be informed, however as the external organisation (i.e. the school) holds primary safeguarding responsible, research staff should facilitate reporting the incident through the school's process. Following this, an AE/SAE form will be completed that *does not* include identifiable information or details of the concern/event, rather only that a safeguarding concern was identified and reported to the relevant staff member at the school and whether they actioned the concern or not (if known). The CI will inform the University of Bedfordshire's Safeguarding team that an issue was reported to the school with primary safeguarding responsibility and whether or not further action was taken (if known). The CI *will not* disclose personal information or details of the event/concern, only that a concern was identified and reported.

Data Protection

The University of Bedfordshire and the University of York will be joint Data Controllers who also process data. Data subjects are the participants in the evaluation, which includes children in participating schools, their parents/carers and staff members in participating schools.

Personal data will be processed under Article 6 (1) (e) (*Processing necessary for the performance of a task carried out in the public interest*) and Special Category data under Article 9 (2) (j) (*Processing necessary for ... scientific ... research purposes)* of the General Data Protection Regulation (GDPR; 2018).

All participant data will be treated with the strictest confidence and will be stored in accordance with the GDPR. For the purposes of the trial, data sharing agreements will be put in place between the research team's institutions where relevant. Any sharing of data between research team institutions will be made explicit in all participant information sheets.

The study consent form will include statements affirming agreement with sharing anonymised data. Anonymous data may be kept indefinitely by the research team, and potentially shared with other research teams.

Potential participants of the trial will be informed about the research via an information sheet sent on behalf of the research team by schools to parents/carers/children/staff. Parents/carers willing for their child to participate will provide written informed consent. Schools will be responsible for ensuring that the personal details of children not participating in the trial are not shared with the research team. Paper consent forms will be securely transported and stored in a locked filing cabinet at the University of Bedfordshire. A unique trial identification number (Trial/Child ID) will be generated for each participant.

For the purposes of the research, the following details about participating children will be collected: child full name, date of birth, gender, FSM/Pupil Premium eligibility, EAL and EHCP status and other measures and assessments as listed above. Schools will transfer personal data directly to the University of Bedfordshire on an encrypted spreadsheet of participant details via a secure file transfer service.

Data collected on paper are: the parent/carer and Teaching Assistant consent forms, which contain identifying personal data, and the parent/carer questionnaires, . Paper consent forms and questionnaires will be returned to the school before secure transfer to the University of Bedfordshire's premises by a researcher, where they will be stored in a locked filing cabinet.

The TPS, CELF-5 subscales and ERRNI assessments will be audio-recorded on a secure encrypted recording device. Recordings will be deleted from the audio-recorder by the University of Bedfordshire researcher after they have listened back, scored the assessment and entered into the trial database.

Audio-recordings from focus groups and interviews will be transferred by the RA from the secure encrypted recording device onto the University of Bedfordshire servers and then removed/deleted from the recorder by the RA. Recordings of interviews and focus groups will be securely transferred to the transcription company via a secure file transfer service and will be deleted from the University of Bedfordshire servers once anonymised transcriptions have been received.

The trial management systems will be held securely by appropriate university systems with access limited to the research team. The dataset for statistical analysis will hold anonymised data. No schools, staff members, or children will be identifiable in the report or dissemination of any results.

Electronic data and paper documents including identifiable personal child data will be securely archived and disposed of by the research team 5 years after the end of the study (2029). Identifiable personal data about adult data subjects (e.g., parents/carers, school staff) will be kept for 5 years after the end of the study (2029). Anonymised electronic data and paper documents will be kept indefinitely.

Data sharing agreements will be put in place with participating schools before data transfer.

The University of Bedfordshire's data protection policy is publicly available at:

https://www.beds.ac.uk/media/23ajvmc0/iasr-privacy-notice-for-research-participants-adults-_april-2021.pdf

https://www.beds.ac.uk/media/2wlpbpxi/iasr-privacy-notice-for-research-participants-accessible-_april-2021.pdf

The University of York's data protection policy is publicly available at:
https://www.york.ac.uk/records-management/dp/

Dissemination Policy

On completion of the trial, the data will be analysed and tabulated and a Final Trial Report will be prepared for NIHR and submitted after ratification by the TSC.

All journal articles published from E-PLAYS-2 will follow the CONSORT Guidelines and checklist to meet the standards required for submission to high quality peer reviewed journals http://www.consort-statement.org/. NIHR will be acknowledged as the funders in all publications.

Participants will be provided with a report of the findings written in a style accessible for lay people, which will be accessible via schools. We will also provide on-going reports through our website as the trial progresses.

In order to disseminate E-PLAYS to professionals, we will offer workshops with the Royal College of Speech and Language Therapists and the children communication charity Speech and Language UK. We will also publicise through the National Association of Professionals concerned with Language Impaired Children (NAPLIC), Autistica, the National Autistic Society and the Communication Trust Consortium. We will also apply to have E-PLAYS registered on websites listing and reviewing evidence-based language interventions e.g., Education Endowment Foundation, the Learning Foundation. Special Educational Needs and Disabilities (SEND) teams in local authorities and Clinical Commissioning Groups (CCGs) are likely to be responsive to efforts to distribute a cost-free product. Should E-PLAYS prove to be effective at the end of this trial, distribution and implementation could start at once as it is a web-based intervention.

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