

# Enhancing pragmatic language skills for young children with social communication difficulties

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/12/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/03/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many children experience difficulties with social communication (also known as pragmatic language ability); that is, the use of language for social purposes. These children struggle with conversational tasks such as appropriate use of greetings, conversational turn-taking, understanding of non-literal language such as jokes, irony or sarcasm, social conventions such as politeness, taking the perspective of the other person and responding with relevant information. These difficulties have profound effects on children's social development, mental health, and education and are strongly associated with bullying, isolation and school exclusion. There is a lack of evidence-based, cost-effective interventions for such children. We have developed a novel approach 'Enhancing Pragmatic Language skills for Young children with Social communication disorder' (E-PLAYS) using a fun computer game. E-PLAYS is for children 5-7 years old and is used by children in pairs. Games designers, teachers, speech and language therapists and children helped us to develop E-PLAYS, and young people with communication difficulties gave feedback.

We carried out two previous studies: a pilot trial and a feasibility study. These studies show that children receiving E-PLAYS scored better on language tests, used more appropriate verbal communication and showed more enjoyment of social interaction than a similar group of children who didn't receive E-PLAYS. The studies also showed that enough children agreed to take part, that schools' teaching assistants could deliver E-PLAYS the programme faithfully to the manual and that teaching assistants and children rated the game as fun and enjoyable. A 4-minute video of two children playing E-PLAYS is available at: [https://drive.google.com/open?id=1n3TFFJ57HOLMDK5IDd4eHLKcEL\\_f4ZR2](https://drive.google.com/open?id=1n3TFFJ57HOLMDK5IDd4eHLKcEL_f4ZR2). Our two previous studies were run with small numbers; we now want to run a large trial and follow up with children after 40 weeks to find out whether E-PLAYS could be delivered effectively by teaching assistants in many schools and whether it is cost-effective to do so. If it is, we will be able to distribute E-PLAYS potentially to all schools in the UK. If we show that E-PLAYS is effective for children with social communication difficulties, we would be able to make it available immediately, together with an online manual, free of charge to all schools in the UK. Against a backdrop in 2020 where children's socialisation with peers, communication skills and peer relations have suffered and the most deprived

individuals have been hit the hardest, E-PLAYS is aiming to develop children's social and collaborative skills by making novel use of technology and is likely to be welcomed by schools, parents and children.

**Who can participate?**

Children aged 5-7 years old whose teachers consider them to have social communication difficulty in state primary schools or special schools

**What does the study involve?**

We will ask schools to take part in the study, we will measure children's pragmatic language skills before and after using E-PLAYS for 10 weeks with their teaching assistants and a partner child from their class. Their teachers will observe classroom behaviours to see if they notice any differences. We will observe and interview children to see whether they like using E-PLAYS and we will observe and interview teaching assistants and also ask them to complete a survey and take part in a focus group to see how they use E-PLAYS, if it fits well into their school day, if they feel confident with it and if they think the instructions are clear. We will ask the child's parent /carer to complete surveys which will tell us about the child's health.

**What are the possible benefits and risks of participating?**

E-PLAYS is a low-cost and effective tool targeting a specific group of children who are currently poorly supported by technology, and we expect the project to demonstrate significant benefits to their communication skills from using it. We do not anticipate any risks to children taking part.

**Where is the study run from?**

University of Bedfordshire (UK)

**When is the study starting and how long is it expected to run for?**

September 2021 to January 2025

**Who is funding the study?**

National Institute for Health Research (NIHR) Public Health Research (PHR) Programme (NIHR131745) (UK)

**Who is the main contact?**

Dr Suzanne Murphy, [Suzanne.Murphy@beds.ac.uk](mailto:Suzanne.Murphy@beds.ac.uk) (UK)

## **Contact information**

**Type(s)**

Principal Investigator

**Contact name**

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**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
315014

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
CPMS 52840, IRAS 315014

## Study information

**Scientific Title**  
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

**Acronym**  
E-PLAYS-2

**Study objectives**  
For young children with social communication difficulties, E-PLAYS is effective and cost-effective, by comparison with usual care, for improving pragmatic language skills at long-term (40 weeks) follow-up

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 23/02/2022, The Ethics Committee of the Institute for Health Research (University of Bedfordshire, Institute for Health Research, Putteridge Bury, Hitchin Road, Luton, Bedfordshire, LU2 8LE, UK; +44 (0)1234 400400; EthicsIHR@beds.ac.uk), ref: IHREC971

## **Study design**

Cluster-randomized controlled study

## **Primary study design**

Interventional

## **Secondary study design**

Cluster randomised trial

## **Study setting(s)**

Community

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Disorders of psychological development

## **Interventions**

The E-PLAYS programme is built around a computer game for two players with 10 weekly sessions, 30 minutes each; teaching assistants supervise all sessions. Children play the game with a teaching assistant for 5 sessions and a classmate for 5 sessions. During their sessions teaching assistants play the game to guide 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.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Pragmatic language skills measured using the Test of Pragmatic Skills (TPS) at baseline and 35-40 weeks post-randomisation

## **Secondary outcome measures**

1. Pragmatic language skills measured using the test of Pragmatic skills at baseline and follow-up at 15-20 weeks post-randomisation

2. Specific language skills measured using the Clinical Evaluations of Language Fundamentals-5 (CELF-5) subscales Recalling sentence and Following Directions at baseline, 15-20, weeks and 35-40 weeks post-randomisation
3. Specific language skills measured using the Expression, Reception and Recall of Narrative Instrument (ERNRI) at baseline, 15-20, weeks and 35-40 weeks post-randomisation
4. Perspective-taking skills measured using the Doodles Task at baseline, 15-20 weeks and 35-40 weeks post-randomisation
5. Perspective-taking skills measured using the Communication Test at baseline, 15-20 weeks and 35-40 weeks post-randomisation
6. Quality of life measured using the Child Health Utility (CHU-9D) at baseline, 15-20 weeks and 35-40 weeks post-randomisation
7. Health-related quality of life measured using the EQ-5D-Y at baseline, 15-20 weeks and 35-40 weeks post-randomisation
8. Resource use measured using a bespoke questionnaire at baseline, 15-20 weeks and 35-40 weeks post-randomisation
9. Communication impairments measured using the Children's Communication Checklist-2 (CCC-2) at baseline 15-20, weeks and 35-40 weeks post-randomisation
10. Behavioural, emotional and peer problems measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 15-20 weeks and 35-40 weeks post-randomisation
11. Pragmatic language skills among partner children (those without a social communication difficulty) measured using the Test of Pragmatic Skills (TPS) at baseline, 15-20 weeks and 35-40 weeks post-randomisation

**Overall study start date**

01/09/2021

**Completion date**

15/01/2025

## Eligibility

**Key inclusion criteria**

School inclusion criteria:

1. State-funded infant or primary school or special needs school with year groups 1-3
2. Schools that have computer facilities (two available laptops) for children to use
3. Agree to all requirements outlined in the E-PLAYS-2 Memorandum of Understanding and Data Sharing Agreement

Focal child inclusion criteria:

1. Children aged 5-7 years old
2. Children who meet the criteria for social communication difficulties as determined by the Social Communication Behaviour Checklist completed by the child's teacher
3. Children whose parent/carers provide consent for them to take part in the E-PLAYS-2 trial
4. Children who complete all the research assistant administrated baseline assessments
5. Child's parent/carer willing to complete relevant questionnaires

Partner child inclusion criteria:

1. Children aged 5-7 years old
2. Children who do not meet the criteria for social communication difficulties as determined by the Social Communication Behaviour Checklist
3. Children whose parents/carers provide consent for them to take part in the E-PLAYS-2 trial

**Participant type(s)**

Healthy volunteer, Patient

**Age group**

Child

**Lower age limit**

5 Years

**Upper age limit**

7 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 800; UK Sample Size: 800

**Total final enrolment**

821

**Key exclusion criteria**

School exclusion criteria:

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

**Date of first enrolment**

01/03/2022

**Date of final enrolment**

30/04/2024

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Marlborough Primary School**

Marlborough Hill

Harrow

United Kingdom

HA1 1UJ

**Study participating centre**  
**Denbigh Primary School**  
Denbigh Road  
Luton  
United Kingdom  
LU3 1NS

**Study participating centre**  
**The Meads Primary School**  
Sawtry Close  
Luton  
United Kingdom  
LU3 2UE

**Study participating centre**  
**The Welldon Park Academy**  
Wyvenhoe Road  
Harrow  
United Kingdom  
HA2 8LS

**Study participating centre**  
**Mitchell Brook Primary School**  
Bridge Road  
Brent  
London  
United Kingdom  
NW10 9BX

**Study participating centre**  
**St Andrew and St Francis Cofe Primary School**  
Belton Road  
Brent  
London  
United Kingdom  
NW2 5PE

**Study participating centre**

**St Teresa's Catholic Primary School**

Long Elmes  
Harrow Weald  
United Kingdom  
HA3 6LE

**Study participating centre**

**Kenmore Park Infant and Nursery School**

Moorhouse Road  
Kenton  
Harrow  
United Kingdom  
HA3 9JA

**Study participating centre**

**Wembley Primary School**

East Lane  
Wembley  
United Kingdom  
HA9 7NW

**Study participating centre**

**Camp Primary and Nursery School**

Camp Road  
St Albans  
United Kingdom  
AL1 5PG

**Study participating centre**

**Divine Saviour Roman Catholic Primary School**

Broomfield Rise  
Abbots Langley  
United Kingdom  
WD5 0HW

**Study participating centre**

**Margaret Wix Primary School**

High Oaks  
St Albans  
United Kingdom  
AL3 6EL



**Study participating centre**  
**Windermere Primary School**  
Windermere Avenue  
St. Albans  
United Kingdom  
AL1 5QP

**Study participating centre**  
**Wigmore Primary**  
Twyford Drive  
Wigmore Primary School  
Luton  
United Kingdom  
LU2 9TB

**Study participating centre**  
**Hammond Academy**  
Cambrian Way  
Hemel Hempstead  
United Kingdom  
HP2 5TD

**Study participating centre**  
**The Grove Academy**  
Fourth Avenue  
Hertfordshire  
United Kingdom  
WD25 9RH

**Study participating centre**  
**St Mary's Catholic Primary School**  
Dunstable Road  
Caddington  
United Kingdom  
LU1 4BB

**Study participating centre**

**Micklem Primary School**

Boxted Road  
Hemel Hempstead  
United Kingdom  
HP1 2QH

**Study participating centre****Skyswood Primary & Nursery School**

Chandlers Road  
St Albans  
United Kingdom  
AL4 9RS

**Study participating centre****Preston Manor School**

Carlton Avenue East  
Wembley  
United Kingdom  
HA9 8NA

**Study participating centre****St Margaret Clitherow Rc Primary School**

Quainton Street  
London  
United Kingdom  
NW10 0BG

## **Sponsor information**

**Organisation**

University of Bedfordshire

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.beds.ac.uk/>

**ROR**

<https://ror.org/0400avk24>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health and Care Research Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131745

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal within one year of the trial end date. 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 ongoing reports through our website as the trial progresses. In order to disseminate E-PLAYS to professionals, the research team will offer workshops with the Royal College of Speech and Language Therapists and the children's communication charity Speech and Language UK (formerly I CAN). 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, and 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.

**Intention to publish date**

31/12/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: the UK Data Service repository (<https://ukdataservice.ac.uk/>)

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 1.0	21/11/2021	05/12/2022	No	No
<a href="#">Protocol article</a>		13/05/2024	14/05/2024	Yes	No
<a href="#">Protocol file</a>		19/06/2023	19/07/2024	No	No
	version 1.1				