

Enhancing pragmatic language skills for young children with social communication difficulties

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| Submission date 15/09/2022 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input checked="" type="checkbox"/> Protocol |
| Registration date 19/12/2022 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 26/03/2025 | Condition category 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. 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 (UK)

Contact information

Type(s)

Principal investigator

Contact name

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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315014

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 (ERNNI) 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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

7 years

Sex

All

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

United Kingdom

England

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**

Quinton Street

London

United Kingdom

NW10 0BG

Sponsor information

Organisation

University of Bedfordshire

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

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? |
|----------------------------------|-------------|--------------|------------|----------------|-----------------|
| Protocol article | | 13/05/2024 | 14/05/2024 | Yes | No |
| Protocol file | version 1.0 | 21/11/2021 | 05/12/2022 | No | No |
| Protocol file | version 1.1 | 19/06/2023 | 19/07/2024 | No | No |