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Evaluating 'E-PLAYS' for children with social communication impairment

Submission date
05/03/2018

Recruitment status
No longer recruiting

Registration date
03/05/2018

Overall study status
Completed

Last Edited
05/01/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Children with social communication impairments (SCI) struggle to communicate appropriately in social contexts; for example, they misinterpret non-literal language and ignore turn-taking and social conventions. Children with SCI are commonly rejected and victimised by peers, during group work they fail to contribute appropriately, and are often ignored or dominated by peers. SCI is 11 times higher in children excluded or at risk of school exclusion. In adulthood these individuals experience more mental health problems such as anxiety and depression, lower academic achievement and make fewer friends. Impairments in social communication therefore have profound effects on children's social development, mental health, and education. Although social communication difficulties are a hallmark of autism spectrum disorders, many other children without autism diagnoses are also affected and few evidence-based, cost-effective interventions are available. A new approach has been developed called E-PLAYS (Enhancing Pragmatic Language skills for Young children with Social communication disorder) using a fun computer game. A study showed significant improvements on a communication test and enjoyment of social interaction by children who received E-PLAYS compared to a group who did not receive E-PLAYS when this was delivered by university-trained postgraduate research assistants. The aim of this study is to assess the feasibility of designing and conducting a full-scale study to find out whether E-PLAYS can be delivered effectively by NHS speech and language therapists working with school teaching assistants instead of being delivered (as in the previous study) by university-trained research assistants. The aims are to find out whether enough speech and language therapists and children could be recruited from NHS trusts for a full-sized study, how acceptable they find E-PLAYS, and to gather information on how best to run a full study.

Who can participate?
Children between the ages of 4 and 7 (inclusive) attending mainsteam primary schools in North-East London who are on the caseloads of NHS speech and language therapists employed by the North-East London Foundation NHS Trust (NELFT)

What does the study involve?
Speech and language therapists are randomly allocated to receive either immediate training on the E-PLAYS intervention or to receive training at the end of the study (control group). Children

in the intervention group receive 11 sessions of E-PLAYS over 7 weeks within school. The E-PLAYS computer game and associated intervention are delivered by teaching assistants who are trained and receive support from speech and language therapists. For some E-PLAYS sessions, the child plays the game with a typically-developing classmate peer (supervised by a teaching assistant), for others, they play with the teaching assistant directly who highlights and encourages the use of communication strategies. Children in the control group continue to receive treatment as usual from their NHS speech and language therapists through their schools. All children are tested at the start of the study and after 15 and 35 weeks to see if their communication has improved.

What are the possible risks and benefits of participating?
The possible benefits of E-PLAYS are that, unlike most computerised interventions for children with autism or other communication difficulties which are single-user games, it provides a structure to support children to play a collaborative game with peers. The computer game has been designed and tested to maximise motivation by providing easy stepped goals for the children to work through and frequent encouragement and rewards with colourful illustrations and fun features. If the findings of the previous study are replicated in this context, the communication and collaboration skills of the children are expected to improve. There are no anticipated risks with participation.

Where is the study being run from?
1. University of Bedfordshire (UK)
2. North-East London Foundation NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2017 to March 2019

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Dr Suzanne Murphy

Contact information

Type(s)
Scientific

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Protocol serial number
35220

Study information

Scientific Title
Evaluating ‘Enhancing Pragmatic Language skills for Young children with Social communication impairment’ (E-PLAYS): a feasibility study

Acronym
E-PLAYS

Study objectives
This is a feasibility trial to assess the feasibility and acceptability of a future definitive cluster randomised controlled trial (cRCT) evaluating the clinical and cost-effectiveness of an intervention to improve pragmatic language skills in children with social communication impairments (Enhancing Pragmatic Language skills for Young children with Social communication impairments (E-PLAYS)).

E-PLAYS is a computer-based intervention for children with autism and other social communication impairments. The trialists are testing the feasibility of delivery of E-PLAYS to young children with social communication impairments (SCI) by teaching assistants, with training and support given by NHS speech and language therapists. E-PLAYS has been designed to be administered by non-specialists such as teaching assistants in 11 sessions over 7 weeks.

Children with SCI are frequently overwhelmed by the complexity and unpredictability of social interaction. E-PLAYS supports children to communicate and collaborate with each other in a computer game format using the script approach developed within cognitive psychology (for a review see Fischer et al., 2007). Scripts may be described as scaffolds that provide a structure for interaction between children. Properly designed, use of a computer-regulated script can:

1. Provide a series of satisfying communication goals that can be tailored to just the right skill level for individuals (Piper et al., 2006)
2. Support communication by structuring collaboration between children so that they solve problems in partnership (Cress et al., 2011, Gal et al., 2015)
3. Incorporate joint virtual prizes to reward children for effective communication and cooperation (Piper et al., 2006)
4. Sustain interest and add fun with surprises, colourful animations and unusual sounds (Ploog et al., 2013, Grynszpan et al., 2014)

Previous studies (Murphy et al., 2014a, 2014b) report the development and evaluation of E-PLAYS (previously called Maze Game) in a pilot RCT. Children receiving E-PLAYS showed significant improvements on: (i) the Test of Pragmatic Skills (Shulman, 1986) (ii) observed use of questions and statements (iii) enjoyment of social interaction.

This is a feasibility trial; the main outcome (i.e., evaluation of effectiveness of E-PLAYS to improve children's pragmatic language skills) will therefore not be determined in this study but left to a subsequent main trial. Assessment of feasibility outcomes will inform whether

progression to a full -scale trial is viable and will indicate any necessary adjustments (changes to procedures, outcome measures, data collection methods, intervention delivery etc.).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge Central Research Ethics Committee, 04/10/2017, REC ref: 17/EE /0320, IRAS Project ID 227864

Primary study design
Interventional

Study design
Feasibility study with two-arm cluster randomised controlled trial design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Children with social communication impairments

Interventions
Participating children with social communication impairment will be cluster randomised, with randomisation at the level of their treating speech and language therapist. Speech and language therapists will be randomised 1:1 to receive either immediate training on the E-PLAYS intervention or to receive training at the end of the trial, via minimisation. The baseline factors which will be used in the minimisation are the cluster size (i.e. the number of children recruited by a given speech and language therapist) and the team (within the NHS trust, NELFT) of the speech and language therapist. The minimisation will be implemented by the trial statistician at the York Trials Unit using MinimPy version 0.3. Once the allocations have been generated they will be communicated to members of the study team responsible for training the speech and language therapists, while ensuring that outcome assessors remain blind to these allocations.

Children in the intervention group will receive 11 sessions of E-PLAYS over 7 weeks. Children randomised to the control group will continue to receive treatment as usual from their NHS speech and language therapists via their schools. The trialists will test children at baseline, 15 weeks after randomisation and 35 weeks after randomisation to see if their communication has improved.

Intervention Type
Behavioural

Primary outcome(s)
The primary aim of this study is to establish the feasibility of a future definitive randomised controlled trial. The main outcome (i.e., evaluation of effectiveness of E-PLAYS) will not be determined in this feasibility trial but left to a subsequent main trial. Assessment of feasibility outcomes will inform whether progression to a full-scale trial is viable and will indicate any necessary adjustments (changes to procedures, outcome measures, data collection methods, intervention delivery etc).

This study has the following feasibility objectives to assess:
1. Whether sufficient numbers can be recruited (via NHS trusts and schools) and retained for a future trial, considering participation, dropout and completion rates
2. The acceptability of E-PLAYS to children, speech and language therapists, teachers, parents and teaching assistants through participation rates and qualitative methods
3. Treatment fidelity through quantitative and qualitative assessments
4. The suitability of outcome measures via response rates and levels of missing data
5. The feasibility of collecting health economic measures and of determining cost-effectiveness for a full trial
6. Parameters required for the identification of the sample size required for a full-scale trial

Key secondary outcome(s)
All outcomes will be measured at baseline, immediately post-intervention (15 weeks post-randomisation) and follow-up (35 weeks post-randomisation):
1. Pragmatic language skills will be measured using the Test of Pragmatic Skills (Shulman, 1986)
2. Communication and speech will be measured using the Children's Communication Checklist (Bishop, 2003)
3. Children's classroom behaviours and peer relations will be measured using the Strengths and Difficulties Questionnaire (Goodman, 2005)
4. General formal language and comprehension will be measured using the Clinical Evaluation of Language Fundamentals (Celf-5) Recalling Sentences subscale (Semel, Wiig & Secord, 2017)
5. Qualitative observations of the children's interactions in a non-computerised collaborative construction task and of the teaching assistants' delivery of E-PLAYS and children's participation
6. Focus groups, interviews and a short bespoke questionnaire will be used to ask speech and language therapists and teaching assistants their opinion of training and of intervention delivery for E-PLAYS
7. Economic outcomes (EQ-5D-5L, PedsQL, and bespoke resource use questionnaires) measured at 35 week follow up

Completion date
31/10/2018

Eligibility

Key inclusion criteria
SLTs will review their caseloads and identify suitable children aged 4 – 7 years using the Social Communication Behaviour Checklist devised by Adams et al (2012):
1. The child has trouble understanding and interpreting the social context and friendship, e.g. social roles, emotions
2. The child has trouble understanding and/or using non-verbal aspects of communication, e.g. facial expression, intonation
3. The child has trouble with aspects of conversation, e.g. beginning and ending, taking turns, giving relevant and sufficient information
4. The child makes bizarre, tangential or inappropriate comments
5. The child has difficulty using and understanding non-literal language
Children are required to meet two out of the five criteria above

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Child

Lower age limit
4 Years

Upper age limit
7 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
Hearing, visual or physical impairment severely affecting speech production

Date of first enrolment
01/12/2017

Date of final enrolment
20/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North-East London Foundation NHS Trust (NELFT)
Goodmayes Hospital
157 Barley Lane
Ilford
United Kingdom
IG3 8XJ

Sponsor information

Organisation
North East London Foundation NHS Foundation Trust

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0416-20035

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in non-publically available repositories within the Universities of York and Bedfordshire by the end of 2019. Anonymised data may be accessed and analysed by members of the project team and with researchers collaborating with members of the project team on the analysis of these data. Consent from participants was not sought for sharing raw data publicly. Therefore, external researchers seeking to access the data for use in future projects must do so via a request to the Chief Investigator (or her delegate), and projects using the data must have been approved in accordance with contemporary UK ethical and regulatory processes pertaining to the release of anonymised data under these circumstances.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/01/2021	05/01/2021	Yes	No
Protocol article	protocol	08/06/2019	17/06/2019	Yes	No
HRA research summary			28/06/2023	No	No