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HoPS: Home-based picture exchange communication schedule (PECS) study

Submission date
05/11/2019

Recruitment status
No longer recruiting

Registration date
26/06/2020

Overall study status
Completed

Last Edited
14/05/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The emergence of language is crucial for social and emotional development but it is estimated that up to 30% of individuals with autism fail to develop functional speech. Furthermore, once they reach school age, many autistic children with little or no language fail to make progress and rarely develop compensatory strategies, such as gesture, to communicate basic needs. This has a negative impact on individuals and their families and increases the risk of children developing emotional and behavioural problems. Currently, most intervention including speech and language therapy is provided in schools. Thus, parents are rarely involved in interventions such as The Picture Exchange Communication System (PECS) and cannot therefore develop these skills at home. PECS was specifically designed to help pre-verbal children with autism make spontaneous requests for basic needs i.e. food, play or leisure activities. Evidence for the effectiveness of PECS with children with autism is promising but limited. The aim of this study is to find out whether it is possible to recruit and deliver the PECS training to parents/carers and their children at home and to ask the families about the acceptability of this approach in order to design a much larger study that can test the benefit of the therapy.

Who can participate?
Children aged 2-10 with a clinical diagnosis of autism who are non/minimally verbal (i.e. fewer than 10 words used on a regular basis)

What does the study involve?
Participants are assessed at three timepoints: first when they are recruited to the study, then again at 20 weeks after they start and finally at 24 weeks after they start. Some assessments are only done at the start of the study i.e. a direct measure with the researcher to measure the child's development and questionnaires for the parents/carers about the child's autism symptoms and general development. Other assessments are done at all timepoints e.g. vocabulary development. Parents are also asked to use a phone App to note down the way in which their child makes requests and at the same time to use a mini-camera to record their child's communication. These measurements are taken for two brief periods (i.e. 1-2 hours) after school and at a weekend and are agreed with the parents. The researchers also ask families about their experience of participating in the study and about the types of local treatment they have received while participating in the study. Participants are randomly allocated either to:

1. Home-based PECS treatment (32 families). Families in this group receive the PECS treatment in addition to their local provision (education and health services)
2. Treatment as usual (32 families). TAU families continue to receive the local provision (education and health services) for their child.
Parents in both groups are invited to attend a short group session where they are informed about the study and the senior researchers can help with any problems relating to the use of the mobile phone App or mini-cameras. In addition, the parents in the TAU group have a session on communication and behaviour management strategies at home. The parents in the PECS group learn about the treatment which is a system for teaching children to communicate using pictures. It involves six stages, each focusing on specific communication skills and uses strategies to teach children to exchange a picture-card or object for an immediate high-value reward (e.g. favourite food).

What are the possible benefits and disadvantages and risks of taking part?
All children in this study will have assessments from a skilled professional and families will complete questionnaires that may help clarify the strengths and needs of their child. If requested the researchers can provide a brief written summary of the assessment data. All parents will be invited to attend a parent education day run by a senior researcher/clinician in the team to inform them about general strategies to improve communication and behavioural management in children with autism. The researchers do not anticipate that this study will result in any disadvantages or risks to families and PECS has not been found to have any unwanted effects in previous studies. For all families there is a time commitment required for the assessment visits. For families allocated to the PECS intervention, additional time is needed for therapy sessions and home practice. This may have effects on family life. The researchers will try to schedule sessions at times to suit each family, including outside normal working hours if necessary.

Where is the study run from?
Evelina Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2019 to December 2021

Who is funding the study?
Autistica (UK)

Who is the main contact?
Dr Vicky Slonims
vicky.slonims@gstt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Vicky Slonims

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Additional identifiers

Protocol serial number
Autistica Funder - ID: 7262 - Grant Reference: 7262

Study information

Scientific Title
A pilot evaluation of a home-based Picture Exchange Communication Schedule (PECS) intervention for young non- or minimally-verbal children with autism

Acronym
HoPS

Study objectives
1. It is feasible and acceptable to teach the use of PECS to parents and their young autistic child at home.
2. It is feasible to use Early Years special school education services as a means to identify and recruit young children with autism in the London area.
3. A mobile App will be an acceptable and efficient method for parents to count and rate their child's spontaneous requesting in the home context.
4. It is feasible and acceptable to use small body cameras (worn by the child) to gather direct observational data on spontaneous communication behaviour at home.
5. Pilot data, including retention rate, assessment completion and effect size, will be collected in order to prepare an application for a large multi-site RCT of home-based PECS training for parents of non-verbal young children with autism in the UK.
6. A short term follow-up, 4 weeks after the cessation of training can be conducted to monitor the continuing use of PECS at home and any sustained progress made by the child.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 25/09/2019, PNM Research Ethics Subcommittee, King's College Hospital (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, United Kingdom; 0207 848 4020; rec@kcl.ac.uk), ref: HR-19/20-14197
2. Approved 15/04/2021, PNM Research Ethics Subcommittee, King's College Hospital (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, United Kingdom; 0207 848 4020; rec@kcl.ac.uk), ref: RESCM-20/21-14197

Primary study design
Interventional

Study design
Single-centre feasibility and pilot randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Autism

Interventions
Blocks of 6-8 parents at each school will be randomised to receive the PECS intervention or Treatment as Usual (TAU). A freely available random number allocation website will be used e.g. Random Allocation Software (RAS) or Research Randomiser. The research assistant will be blind to group allocation. Children will be stratified into two age groups (+/- 4 years) to avoid large differences between PECS and TAU groups. Eligibility criteria should mean that differences in language ability and autism severity are unlikely. Any possible differences in cognitive or other abilities will be explored in analysis. Qualitative data will be used to assess the acceptability of the study to families and to the therapist.

The delivery of the Picture Exchange Communication System (PECS) will be tested. PECS is a well-established manualised system for teaching children to communicate using pictures or objects. It involves 6 developmental stages, each focusing on specific communication skills. PECS uses behavioural strategies to teach children to exchange a picture-card or object for an immediate high-value reward (e.g. favourite food). Initially, teaching is primarily through the use of physical prompts, which are subsequently systematically faded to ensure independence.
Stage 1: focuses on teaching the child to exchange an image to receive a highly desirable item (often food). Prompts are given by a second adult and prompting is then gradually reduced.
Stage 2: develops a child's persistence by creating small barriers to communication such as increasing the distance between the child and the desired object/activity.
Stage 3: more images of desired items are introduced and the child begins to discriminate between them to make requests.
Stage 4: combines images in a "picture strip" to indicate messages such as 'I want….', thereby helping the child to use more complex constructions.
Stages 5 and 6: build on these skills to help a child learn to answer questions (e.g. what do you want?) and to make comments (e.g. what can you see?)
The therapist will provide 6 weekly sessions at home with the parent and child, followed by a further 6 home-based sessions for the parent only on a fortnightly basis, giving a total of 12 sessions over 18 weeks. Home-based sessions and assessments will be arranged to fit in with parents' commitments.

Parents in each group will be invited to attend a brief group workshop hosted by the school and delivered by the research leads. Parents in the TAU group will be provided with psycho-educational information about autism, and given strategies to support communication and behaviour management. The parents in the PECS group will be introduced to the intervention. Both groups will be given general information about how the study is to be conducted and have the opportunity to discuss the use of the App and the mini camera.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 12/03/2021:

1. Successful recruitment of 64 eligible participants, measured using evaluation of participant numbers in each school (anticipated to be 4- 5 schools).
2. Successful data collection on questionnaire and direct assessments at relevant time points e. g. measurement of complete data sets for all recruited participants at each assessment point: baseline, end point (18 weeks) and follow up (22 weeks) and assessment of complete data sets for all recruited participants at the end of data collection for the study.
2.1. Autism symptoms: The Social Communication Questionnaire - Lifetime version
2.2. Communication: Communication Development Inventory (CDI) Words and Gestures
2.3. Adaptive Behaviour: The Adaptive Behaviour Assessment System (ABAS)
2.4. Developmental level: Researcher administered Mullen Scales of Development
2.5. Qualitative data e.g. A therapist rating (5 point scale), A parent-completed Social Validity Questionnaire
2.6. Local service use data: from parent completed Child and Adolescent Service Use Schedule (CA-SUS)
3. Acceptability of App and body-worn cameras and quality of data obtained from this equipment, measured using verbal feedback from parents at each assessment i.e. baseline, end point(18 weeks) and follow up (22 weeks).
4. Number of families retained in both groups, measured using assessment of the number of participating/engaged families at end point (18 weeks) and follow up assessments (22 weeks)
5. Number of home-based sessions delivered by the therapist, measured using therapist diary records at end of each family's treatment (17-18 weeks)
6. Data (from the research therapist) on parent/child progression of PECS stages (i.e. 1-6) for treatment families (parent treatment fidelity) at end of treatment period (17-18 weeks)
7. Feedback on feasibility and acceptability of the intervention at treatment end point (18 weeks) from Parents assessed by Social Validity Questionnaire (for treatment group only). This information will be further supplemented by qualitative data from end-of-treatment interviews conducted by an independent member of the study who will be supervised by Dr Penny Williams (Study co-investigator). An invitation letter will be send to parents in the intervention group and the interviews will be conducted over the phone with randomly selected parents (12 -15 interviews in total, depending on when data saturation is reached). All interviews will be recorded on an audio device and further transcribed for analysis. Each interview will last between 20-45 min and an interview guide will be used. At the end of the study the research assistant and therapist will be asked to provide feedback on their experience of participating in the study.

Previous primary outcome measure:

1. Successful recruitment of 64 eligible participants, measured using evaluation of participant numbers in each school (anticipated to be 4- 5 schools).
2. Successful data collection on questionnaire and direct assessments at relevant time points e. g. measurement of complete data sets for all recruited participants at each assessment point: baseline, end point (18 weeks) and follow up (22 weeks) and assessment of complete data sets for all recruited participants at the end of data collection for the study.
2.1. Autism symptoms: The Social Communication Questionnaire - Lifetime version
2.2. Communication: Communication Development Inventory (CDI) Words and Gestures

2.3. Adaptive Behaviour: The Adaptive Behaviour Assessment System (ABAS)
2.4. Developmental level: Researcher administered Mullen Scales of Development
2.5. Qualitative data e.g. A therapist rating (5 point scale), A parent-completed Social Validity Questionnaire
2.6. Local service use data: from parent completed Child and Adolescent Service Use Schedule (CA-SUS)
3. Acceptability of App and body-worn cameras and quality of data obtained from this equipment, measured using verbal feedback from parents at each assessment i.e. baseline, end point(18 weeks) and follow up (22 weeks).
4. Number of families retained in both groups, measured using assessment of the number of participating/engaged families at end point (18 weeks) and follow up assessments (22 weeks)
5. Number of home-based sessions delivered by the therapist, measured using therapist diary records at end of each family's treatment (17-18 weeks)
6. Data (from the research therapist) on parent/child progression of PECS stages (i.e. 1-6) for treatment families (parent treatment fidelity) at end of treatment period (17-18 weeks)
7. Feedback on feasibility and acceptability of the intervention at treatment end point (18 weeks) from Parents assessed by Social Validity Questionnaire (for treatment group only). Two families randomly selected from each school (one treatment and one Treatment as Usual family) will have a qualitative interview with Dr Penny Williams on their experience of participating in the study. Focus groups to provide feedback on the experience of participating in the study will be arranged within 2 months of completion of the study for teachers in each school. At the end of the study the research assistant and therapist will be asked to provide feedback on their experience of participating in the study.

Key secondary outcome(s)
1. At baseline, endpoint (18 weeks) and follow up (22 weeks) PECS usage (count of requesting behaviours rated by parents via telephone App and by researcher from video), according to 2 codes: 1) use of PECS, 2) other forms of request. Other behaviours (anticipated to be non-communicative behaviour) will be noted.
2. Children's communication assessed by parent-rated Communication Development Inventory (CDI) at baseline and endpoint (18 weeks)

Completion date
10/12/2021

Eligibility

Key inclusion criteria
Children:
1. Aged 2-10 years
2. Clinical diagnosis of autism, meeting cut-off for autism symptoms i.e ≥15 on the Social Communication Questionnaire
3. Non/minimally verbal (i.e. fewer than 10 words used on a regular basis)

Parents:
4. Willing to consent to participation and able to engage in intervention at home

Participant type(s)
Learner/student, Mixed

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
2 Years

Upper age limit
10 Years

Sex
All

Total final enrolment
39

Key exclusion criteria
Children who have:
1. More than 10 words used regularly
2. Severe visual or hearing impairment
3. A twin brother or sister who would also be a candidate for the intervention
4. Parents in whom poor use and/or understanding of English would limit participation

Date of first enrolment
30/09/2019

Date of final enrolment
12/01/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Evelina Children's Hospital (Guy's & St Thomas' NHS Foundation Trust)
Children's Neurosciences
2nd Floor
Becket House
1 Lambeth Palace Road
London
United Kingdom
SE1 7EU

Study participating centre
Russet House School
11 Autumn Cl
Enfield
United Kingdom
EN1 4JA

Study participating centre
Phoenix School
49 Bow Rd, Bow
London
United Kingdom
E3 2AD

Study participating centre
Queensmill School
1 Askham Road
Shepherds Bush
London
United Kingdom
W12 0NW

Study participating centre
Hatton School & Special Needs Centre
Roding Lane South
Woodford Green
London
United Kingdom
IG8 8EU

Study participating centre
Cherry Garden School
41 Bellenden Rd
Peckham
London
United Kingdom
SE15 5BB

Study participating centre
The Livity School
35 Adare Walk

Streatham Wells
London
United Kingdom
SW16 2PW

Study participating centre
Turney School
Turney Rd
Norwood
London
United Kingdom
SE21 8LX

Sponsor information

Organisation
Evelina Children's Hospital, Guy's and St Thomas' NHS Foundation Trust and King's College London

Funder(s)

Funder type
Charity

Funder Name
Autistica

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Current IPD sharing statement as of 10/01/2022:
The anonymised data analysed during the current study will be available upon request from Dr Vicky Slonims (vicky.slonims@gstt.nhs.uk) after the completion of analysis and reporting to the funder in accordance with the permissions under which participants have signed up and agreed for data to be shared. Requests for data will be considered case-by-case on the basis of the purpose of the query e.g. during the publication process or if requested by PNM Research Ethics sub Committee, Kings College London, james.2.patterson@kcl.ac.uk , in accordance with their guidance.

Raw data will include anonymised quantitative descriptive data on participants, the delivery of therapy e.g. dosage etc and some between group analyses. Additionally there will be transcripts from qualitative interviews with participants. Data is stored electronically on databases, on paper in secure locked cabinets in a secure building and video recordings on an encrypted hard drive kept in a secure cabinet.

3-part consent from participants has been obtained for the use of anonymised data in publications and presentations for dissemination etc, the sharing of anonymised data with other research groups, and video or similar being used at conferences and in presentations to professional groups

The data analysed during the current study will be also be included in the subsequent results publication.

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Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Vicky Slonims (Vicky.slonims@gstt.nhs.uk). Data are primarily qualitative relating to the feasibility of the study. Secondary data comprises information from questionnaires, a baseline direct assessment of child development and count ratings from video footage of children's behaviour at home. The data can be applied for up to 3 years following the end of the study in accordance with KCL data storage policy. In addition, the ethics committee have indicated that they may wish to audit the progress of the study. In accordance with the participant information and consent forms the researchers will not share any data without first obtaining the permission of study participants. All data are kept in accordance with KCL ethics requirements, i.e. stored anonymously with personal data and study identification information kept separately; databases are password protected and stored on an NHS electronic file system with limited access (only named study personnel have access to the folder).

IPD sharing plan summary

Available on request, Published as a supplement to the results publication, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5	25/03/2021	10/01/2022	No	No