# 1. GENERAL INFORMATION

## PROTOCOL TITLE

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

## SHORT TITLE/ACRONYM

Home-based PECS Study (HoPS)

## FUNDER

This research is being funded by a charity called Autistica https://www.autistica.org.uk/ UK Registered Charity number: 1107350

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## 2. PROTOCOL AMENDMENTS

Any amendments have been made to the protocol.

## 3. STUDY SUMMARY

*Background:* Many young children with autism enter educational provision without any effective means of communicating their needs. Currently, most intervention including speech and language therapy is provided in schools. Thus, parents are rarely involved in interventions such as PECS and generalisation to the home situation is very limited. The focus of the proposed study is on helping parents of young children with autism to use PECS at home and to monitor outcome using measures that directly reflect children's spontaneous communication in the home setting.

*Overall Aim:* assess the feasibility and acceptability of teaching the use of PECS to parents and young autistic children at home.

*Design:* Feasibility and pilot Randomised Controlled Trial (RCT).

*Participants:* 64 young children (age between 2-10 years). Equal numbers of children will be randomised *at each school* either to: a) PECS treatment or (b) Treatment as usual (TAU) as follows: 32 children in the PECS group; 32 children in the "treatment as usual" group. (b) Treatment as usual (TAU).

## 4. BACKGROUND INFORMATION

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 (11). Furthermore, once they reach school age, minimally verbal children show almost no gains in vocalisations or communicative exchanges over the course of a whole school year (12) and few develop compensatory strategies, such as gesture, to communicate basic needs. This has a significant detrimental impact on individuals and their families and increases the risk of children developing emotional and behavioural problems (13).

The Picture Exchange Communication System (10) (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 (14). The few randomised controlled trials (RCTs) of PECS that have been conducted ([9, 15, 16]) all reported some increases in communication following training but comparisons with alternative interventions produced varying results. Thus, while PECS training resulted in greater improvements in communicative word use than Responsive Education and Prelinguistic Milieu Teaching (16), there were no differences in outcome compared with Pivotal Response Training (15). Furthermore, whilst increases in child initiations in classes where teachers were trained to use PECS were greater than among pupils receiving teaching as usual, treatment effects were not maintained when intervention ceased (9). Other non-RCT studies have reported improved verbal and functional communication (17), with possible reduction in problem behaviours (18) and improvement in social communication (19).

These studies suggest PECS can increase child-initiated communication and some generalisation of the use of PECS to untrained adults or new settings has been reported. However, in a meta-analysis (18) generalisation was reported in only 54% of studies and parent involvement was only included in one study (20). In other studies, although parent training was provided to enhance generalisation, the results were not reported (16). Only one small study (three mothers) has specifically investigated the delivery of PECS in the home setting, finding that this approach was both feasible and acceptable to parents (7). Nevertheless, it is also evident, from an analysis of YouTube videos of parent-led PECS exchanges (21), that the standard of home-based delivery is often inconsistent and is characterised by a high proportion of implementation errors.

In summary, most high quality PECS research to date has been conducted by trained professionals in clinical or education settings (18) rather than at home, despite the fact that this is where children spend a significant proportion of their time. Moreover, the use of PECS in schools is often restricted to snack times, in which requests are cued by the situation rather than being truly spontaneous and unprompted (9). This is contrary to the principles of PECS, which, at least in the early stages, require that rewards are provided *immediately* after every spontaneous request. Although in schools this is impractical, in the home environment spontaneous requests to parents can be rewarded immediately and positively.
The NICE Clinical Guideline (14) recognised the importance of research to improve communication skills in children and young people with autism, specifically highlighting the need to determine whether PECS is "effective in improving spontaneous requesting in non-verbal children with autism across a range of contexts that demonstrate generalisation of skills". In 2015, the James Lind Alliance survey (22), funded by a collection of charities headed by Autistica, identified communication as the second most important area requiring research. Furthermore early intervention for children with disability is a priority in Improving Children and Young People's Health Outcomes (23). This study aims to establish the requirements for a high quality investigation of PECS intervention and is specifically designed to evaluate its impact on communication in the home setting, for young non-verbal autistic children.

## 5. METHODS

### 5.1 STUDY AIMS AND DESIGN:

This Feasibility and pilot randomised controlled trial (RCT) aims to:

a) Evaluate the feasibility and acceptability of teaching the use of PECS to parents and young autistic children at home
b) Test the feasibility of using Early Years and special school education services to recruit young children with autism in the London area
c) Pilot and assess the use of an App designed to enable parents accurately and easily to count and rate their child's spontaneous requesting in the home context
d) Test the feasibility and acceptability of using small body cameras (worn by the child) to gather direct observational data on communication behaviours at home.

e) Provide pilot data, including estimates of retention rate, assessment completion and effect size, 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.
f) Conduct a short term follow-up, 4 weeks after the cessation of training, to monitor the continuing use of PECS at home and any sustained progress made by the child.

## 5.2 PARTICIPANTS

The present feasibility study will focus on young children (between 2 and 10 years of age) since our aim is to explore the possibility of establishing strong independent and functional communication skills as early as possible. A total of 64 young children (N=64) will be recruited in the study.

*Inclusion criteria:*

- Child: age between 2 and 10 years
- Clinical diagnosis of autism spectrum disorder and meeting cut-off for autism symptoms (i.e. ≥15 on the Social Communication Questionnaire)
- Non/minimally verbal (i.e. fewer than 10 words used on a regular basis)
- Parents willing to consent to participation and able to engage in intervention at home.

*Exclusion criteria*: Children who have more than 10 words used regularly; have severe visual impairment; have a twin brother or sister. Parents with reduced levels of spoken and/or understanding of English, which would limit participation.

## 5.3 RANDOMISATION PROCEDURE

*Group assignment* Blocks of 16 parents at each school will be randomised to either: a) PECS treatment or (b) Treatment as usual (TAU); 32 will be allocated in each group for a total sample of 64 (N=64).

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. We will use a freely available random number allocation web site e.g. Random Allocation Software (RAS) or Research Randomiser. VS or PW will contact families to discuss their allocation, the RA will be blind to group allocation.

## 5.4 RECRUITMENT

Participating schools have been approach via the Pan London Autism Schools Network (PLASN). This network was established in 2009 with the collaboration of Autism Speaks and the Institute of Education (UCL), Dr Vicky Slonims, Principal is a co-founder of the group which currently comprises twelve specialist schools. PLASN schools have developed strong links with local universities to focus on research issues that are of particular relevance to staff, pupils and families in the network. The collaboration has previously contributed to a number of research studies involving several of the applicants. All children in PLASN schools have a Statement of Special Educational Needs (SEN) and/ or Education Health and Care Plan (EHCP) with autism as their primary need.

The study team will send an invitation letter to the schools (these schools are part of the PLASN). The contact details of the research team will be included in the letter. Any questions the schools may have will be answered by a member of the research team in person or via email/telephone.

Prior to randomisation, the mobile telephone number of the research assistant will be provided to facilitate arrangements for assessments. Because the research assistant will be blinded to the group allocation, the mobile telephone number of a member of the study team who is not blinded to the group allocation will be provided to the parents after they are randomised to groups. This will prevent any inadvertent information about group allocation being divulged to the research assistant and is consistent with the study design. Mobile telephone numbers provided to participants will be specifically designated for the study.

If the schools are interested in participating, the research assistant and/or the chief investigator will visit the school to meet the senior school collaborators and will give them the information sheet in person (School IS V1 27.08.19). In addition they will discuss the study in detail and establish the criteria for participation to ensure that only families who meet these criteria are informed about the study. If the schools are happy to take part, they will be asked to sign a written agreement (Schools MOA V1 27.08.19) outlining the details of their participation and to send it back to the research team via email or post. This will email will not contain any confidential information about study participants. Alternatively, a member of the research team will collect the signed agreement in person at the school.

School staff will inform parents about the study and will provide them with the Parent Information Sheet (Parent IS 27.08.19) which has contact details of the study team. Parents will be invited to complete a section of the form indicating their agreement or refusal to be contacted by the research assistant. In order to make the process easier for the families they will be asked to return the slip to the school in a sealed envelope (provided by the research team) in the child's school bag. Envelopes will be stored in an agreed location at the school e.g. in the main office so that a member of the study team can collect them at an agreed date. School staff will be asked to remind parents about the request only once to prevent any risk of undue pressure. Afterwards, the research assistant (Ms. Viviana Aya) will contact the interested families via telephone or email and provide full details about the study. Parents will be told that their participation in the study is voluntary and additional to the school curriculum. Also that they will be able to withdraw at any point during the duration of the project (i.e. until the 10th of December 2021). Mrs. Aya will send parents a blank consent form via email or post. Parents will have two weeks to decide if they wish to take part. Parents will be asked to sign the consent form and send it back to the research team via encrypted email or confidential post. Alternatively, parents can give the signed consent form to the study team in person. All parents will be invited to attend a half-day educational workshop hosted at the school and delivered by Dr. Penny Williams or Dr. Vicky Slonims and the research therapist Ms. Thomasin Brooker. Parents will be provided with information about autism, communication, behaviour, other relevant issues and general information about local resources.

The decision as to whether a child will participate in the study will rest with their parent. Children who meet eligibility criteria for participation in the study will have severe autism, significant learning disability, little or no verbal communication and in all likelihood very limited comprehension. The developmental age equivalent of children eligible for the study is likely to be below 18 months of age and they therefore, lack capacity to assent to participation in the study.

Eligibility criteria are provided below for information: a) age 2-10 years b) with a clinical diagnosis of autism spectrum disorder and meeting cut-off for autism symptoms (i.e. ≥15 on the Social Communication Questionnaire) and c) non/minimally verbal (i.e. fewer than 10 words used on a regular basis).

## 6. ASSESSMENTS (see table below for details of time points for assessment)

### 6.1. *Child characteristics*

The following measures, selected to assess children's characteristics, are all widely used in the autism field and are of established reliability and validity.
*i) Autism symptoms:* The Social Communication Questionnaire - Lifetime version (2) is a brief parent/caretaker questionnaire that assesses the presence of autism symptoms
*ii) Developmental level*: The Mullen Scales of Early Learning (MSEL) (3) provide a comprehensive standardised measure of motor, perceptual, and language abilities in children aged from birth to 68 months. Raw scores on each subscale will be transformed to age-normed *t*-scores.
*iii) Communication:* Communication Development Inventory (4) (CDI) Words and Gestures The parent rated version of this questionnaire, designed for typically developing children aged 8-18 months. Raw scores will be used to assess the understanding and use of vocabulary and nonverbal gestural signals. It will also be used at the end of intervention to explore whether there has been any overall change in children's communication skills.
*iv) Adaptive Behaviour*: The Adaptive Behaviour Assessment System (5) (ABAS) which extends from birth to 89 years, is a measure of adaptive skills across 3 major domains: Conceptual, Social, and Practical.

### 6.2. PECS *usage*

PECS is specifically designed to increase spontaneous communication and our focus is on the feasibility of assessing truly spontaneous requests (i.e. unprompted by a task or context) in the home. Changes in such behaviours cannot easily be captured in a short assessment session and recordings made by an unknown observer in the home are likely to interfere with natural communication. Thus, we aim to acquire parent rated and independent verification of the frequency and types of spontaneous requests made by the child at home using two novel approaches to data collection:

a) App for use on smartphones (i.e. Tally Tracker App). Parents will be asked to use the App supplied by the research team, to make frequency counts of: a) requests made using PECS; b) requests made by other means (e.g. speech, vocalisations or gestures etc.);. Any other forms of communication will be recorded in an 'other' category as qualitative data.

The researcher will provide the app and assist all participants in downloading it on their mobile phones. Two app step-by-step guides (i.e. for iPhone and android) will also be given to parents. The app is easy to use and does not involve complex features. Use of the App at these pre-specified times will be prompted by a text from the research assistant Ms. Viviana Aya.

b) Video recording using a very small body camera (approximately 4cm x 2cm), worn by the child (as used by cyclists; see appendices). This equipment will provide corroborative information about the frequency and type of spontaneous communication used by the child at home. Personal communication from two parents who were asked to use the cameras and report back to the study team (one typically developing child and one with autism) have confirmed acceptability after a short period of acclimatisation details). Families will be given a defunct camera prior to the recording sessions in order to allow the child to become comfortable with the device. Cameras will be supplied via the research team. A step-by-step guide on how to use the camera will be provided to parents. All data will be removed from the camera and stored on an encrypted hard drive by a designated member of the study team.

c) Use an App provided by the research team (i.e. Tally tracker App) on their mobile phones in order to record the number and type of requests that their child makes over two specified periods as follows: 1) for 2-3 hours on a weekday after school and 2) for 2-3 hours at a weekend. This data will be collected at three time points during the duration of the study (i.e. pre and post treatment and follow-up) for both groups (i.e. TAU and treatment groups). The researcher will provide the app and assist all participants in downloading it on their mobile phones. The app is easy to use and does not involve complex features.

d) Attach a small video camera (approximately 4cm x 2cm) similar to that used by cyclists and provided by the study team, to their child's clothing to provide direct observations about the frequency and type of spontaneous communication used by the child at home.

**3. Assessments of parent practice and feedback from families - treatment group only (see appendices for examples)**

*i) A simple therapist rating* (5 point scale) on whether the parent understood the PECS stage and process and practiced the intervention will be used after each session to assess the parent's delivery of PECS in the home.

*ii) A parent-completed Social Validity Questionnaire* (7) has been provided by Professor Sheila Morgan of Ohio State University. It will provide feedback on families' experience of participation in the study (e.g. time demands, use of the equipment, relevance of treatment; ease of following the programme). 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. All data collected from the interviews will be anonymised and kept secure and confidential.

### *4. Other provision/interventions currently received.*

The Child and Adolescent Service Use Schedule (8) (CA-SUS) completed by parents will be used to assess the types and amounts of local interventions utilised by families (e.g. speech and language therapy, alternative medicines and other education provision). Staff will be asked about PECS use within the school.

### *5. Short-term follow-up (Intervention group only)*

Previous studies have indicated that PECS use is not maintained once direct intervention has ceased (9). Thus, approximately one month post-treatment, use of PECS at home will be assessed using the App and cameras (as described above) to determine whether families have continued to use the intervention once they are no longer actively involved in therapy and to see if progress by the child has been sustained.
Table 1 summarises the measures to be used at baseline, end of treatment and at short term follow-up.

### *6. Summary of assessment measures*

The following table summarises the measures to be used at baseline, end of treatment and at short term follow-up:

| **Descriptive measures (baseline only)** | **Pre and post treatment measures** | **Post treatment only** | **Follow-up*** |
|---|---|---|---|
| Social Communication Questionnaire | PECS usage (telephone App and video) | Assessment of parent treatment fidelity* | PECS usage* (telephone App and video) |
| Mullen Scales of Development | Communication Development Inventory (CDI) | Feedback on participation using Social Validity Questionnaire* | |
| Adaptive Behaviour Assessment System (ABAS) | | Child and Adolescent Service Use Schedule (CA-SUS) | |

* treatment group only

## 7. INTERVENTION

*Treatment:* PECS is a well-established manualised system for teaching children to communicate using pictures (10). 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?)

In this study we anticipate that most children will complete Stages 1-3.

*Delivery of therapy*: Parents will be provided with detailed information about the study and introduced to the PECS treatment techniques and phases. The therapist will then provide 6 weekly sessions at home with the parent and child, followed by a further 6 home-based sessions on a fortnightly basis, giving a total of 12 sessions over 18 weeks. Timings for home-based sessions and assessments will be arranged to fit in with parents' other commitments. All children will start the PECS treatment at Stage 1 even if they are beyond that phase in school. This is to ensure that parents, who are unlikely to have participated in school based PECS schemes, are confident in using the system. Start and end point Stages for all children will be recorded. A brief summary report will be provided to families at the end of the intervention. This report will detail the number of sessions attended, the progress the child has made and the PECS Phase achieved with a brief description of skills at this PECS Phase.

## 8. STUDY OUTCOMES

As this study is designed as a feasibility study primary outcome data will focus on the following variables:

a) Successful recruitment strategy i.e. recruitment of 64 eligible participants
b) Data collection on questionnaire and direct assessments for all participants at each assessment time point
c) Utility of the App and body-worn cameras and quality of data obtained from this equipment.
d) Retention of families in both groups,
e) Number of home-based sessions delivered by the therapist
f) Evaluation of the PECS stages established for treatment families (parent treatment fidelity)
g) Child and Adolescent Service Use Schedule (CA-SUS) to ascertain local provision
h) Parent, teacher, research assistant and therapist feedback on feasibility and acceptability (Social Validity Questionnaire, focus groups).

The secondary outcome data will focus on the following:

a) PECS usage - (telephone App and video). The RA will extract frequency counts from the App and score episodes of requesting from films (remaining blind to group allocation).

Experience of coding behaviour from video suggests that it should be possible to scroll through the video at a medium-fast forward pace to identify episodes of requesting behaviour and then to score them according to 2 codes: 1) use of PECS, 2) other forms of request (e.g. speech, vocalisations or gestures etc.)

b) Communication Development Inventory (CDI) to explore whether there has been any overall change in children's communication skills.

Additional outcome data:

a) A short anonymous questionnaire to explore children's access to PECS intervention from professionals working with children with autism. The questionnaire will be circulated through professional Clinical Excellent Networks (CENs) via Survey Monkey. It is designed to take under 10 minutes to complete, consisting mainly of multiple choice questions.
b) A short anonymous questionnaire to ascertain if individuals transferring to adult services do so with some skills using PECS and also to establish if PECS is included in treatment for adults. The questionnaire will be sent through professional Clinical Excellence Networks (CENs) to professionals working in adult therapy services via Survey Monkey. It takes under 10 minutes to complete and is mainly comprised of multiple choice questions.

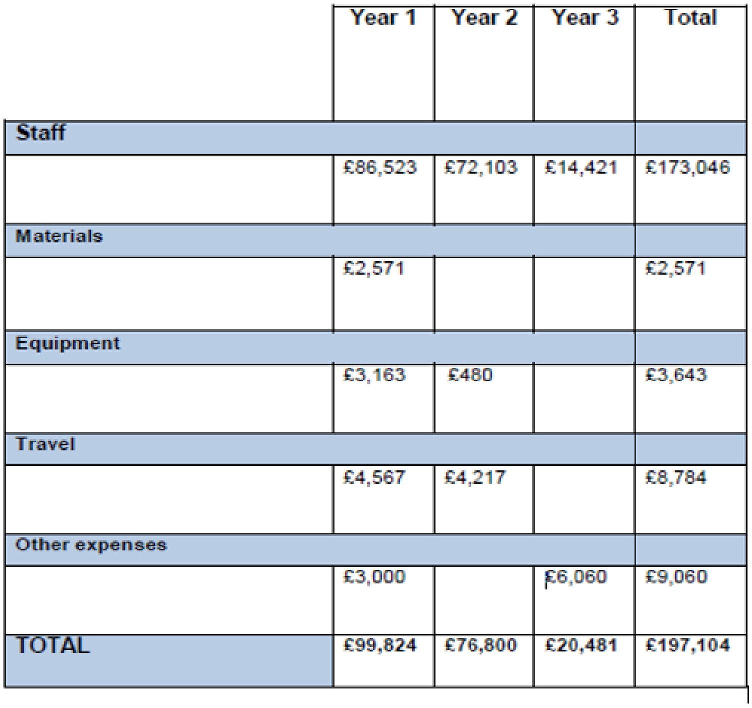
## 9. STATISTICAL ANALYSIS

The similarity of data derived from the App and video will be compared to establish the respective value of these sources of data. Parental counts (via telephone App) and video recordings of number of spontaneous requests used by the child will be analysed using intention-to-treat approach in a mixed ANOVA model, accounting for clustering within school and covarying for baseline score on the same measure. This will inform the sample size for a possible full randomised control trial. A preliminary power calculation *(*2-tailed p=.05 and assuming 10% drop-out or failure of equipment) indicates that the study has 47% power, for an effect size of 0.5 and 62% power for an effect size of 0.6 on the secondary measure of rate of spontaneous requests using PECS. Change in vocabulary use (assessed by the CDI) will also be compared across groups. In addition we will explore the impact on outcome of child characteristics e.g. age, developmental level and parental fidelity to treatment as rated by the therapist (see measures)**.**

## 10. TIMESCALE FOR THE PROJECT

The duration of the project will be 32 months. The expected completion date of the project is 10/12/2021.

## 11. COSTING FOR THE PROJECT



| | Year 1 | Year 2 | Year 3 | Total |
|---|---|---|---|---|
| **Staff** | | | | |
| | £86,523 | £72,103 | £14,421 | £173,046 |
| **Materials** | | | | |
| | £2,571 | | | £2,571 |
| **Equipment** | | | | |
| | £3,163 | £480 | | £3,643 |
| **Travel** | | | | |
| | £4,567 | £4,217 | | £8,784 |
| **Other expenses** | | | | |
| | £3,000 | | £6,060 | £9,060 |
| **TOTAL** | £99,824 | £76,800 | £20,481 | £197,104 |

## 12. ETHICS AND REGULATORY APPROVALS

*Ethical approval*
The sponsor site is Evelina Children's Hospital (GSTT) but the participants will be volunteers (parents) recruited through schools. We will approach the senior management teams or relevant individuals with ethical oversight at participating schools. The R&D department of Evelina Children's Hospital (GSTT NHS Foundation Trust) have reviewed the application, provided research costings and advised the researchers that NHS ethical approval is not required for this study. However, we will seek KCL and local R&D approval.

*Data handling and confidentiality*
Data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR). All research data is stored separate from personal data, using a unique code. Any information shared with third parties will be anonymised. No video or audio data will be used without consent. All information which is collected during the research will be kept strictly confidential as follows:

a) Paper assessments such as questionnaires, contact details, consent forms and correspondence with families and schools. These will stored in such a way as to keep study identity numbers and personal details (i.e. contact details) separately. These papers will be collected from parents or school staff in person unless there is agreement for them to be posted or sent by encrypted email to the study team. We will store all therapy related papers in a locked cabinet in a secure location at the Evelina Children's Hospital (Becket House) and research documents at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN) (Henry Wellcome Building).

b) The tally counts from parents' mobile phones will be easily downloaded by parents and send to a nominated member of our research staff via encrypted email. These data will be stored on an encrypted external hard drive by a designated member of the research team.

c) Video recordings from the camera will be downloaded and stored in an external encrypted hard drive by a member of the research team. Only authorised members of the research team will have access to this data.

d) Computer files will be stored on devices that are encrypted (protected) and kept separately in password protected storage.

e) No identifying information will appear on any other reports or presentations produced by the study team. For further educational use of these video clips, for example for research dissemination, participants will be contacted and consented in all cases.

*Data Protection Statement*

The data controllers for this project will be Evelina Children's Hospital (Guy's and St Thomas' NHS Trust and King's College London (KCL). Personal data will be processed for the purpose of the research outlined above. The legal basis for processing personal data for research purposes under GDPR is a 'task in the public interest' Participants will provide consent for the use of your personal data in this study by completing the study consent form.

## 13. PUBLICATION

The results of the research will be targeted for publication in peer-reviewed journals of general and special interest. The study will also be disseminated in collaboration with Ian Dale and Denise May at the National Autistic Society (NAS), will focus on three stakeholder audiences: (1) health practitioners, education professionals and researchers, (2) autistic people and their families, and (3) study participants. We aim to ensure that all three groups are fully informed about the project.

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## 15. APPENDICES

### 15.1 COVID-19 PROTOCOL DEVIATION 1

#### a) Study timeline

- The study activities have been paused since Friday 3rd April 2020.
- A total of 33 families have been recruited so far from three schools. Details of the assessments and the therapy delivery for each group of families are as follows:

| Group of families | Assessments | Therapy |
|---|---|---|
| School 1 | Completed | Completed |
| School 2 | Partially completed (post & follow-up assessments) | Not completed |
| School 3 | Completed (baseline assessments) | Aim to be delivered at a delayed date (i.e. during the summer) |

- A fourth school has already agreed to take part in the study. Recruitment for this school is aim to be completed during the autumn.

#### b) Letters to parents and schools

Letters will be sent to all participating parents and schools to let them know that the study has been paused during the period of ´lock down´ and that the study activities (including recruitment and delivery of therapy) will be resumed as soon as we will be able to.

### 15.2 COVID-19 PROTOCOL DEVIATION 2

#### a) Recruitment

- Due to the lock-down regulations and the high demand on NHS staff, recruitment of new participants had to cease on 12/01/2021.

- Four new schools were approached by the study team at the end of 2020. Schools have sent invitation letters to families and the study team has received expressions of interest from families. We did not progress to obtaining consent from the families.
- The study team will write to families who expressed an interest in taking part in the study to explain the circumstances in which we need to close recruitment.
- The study team will contact the four new schools to inform them about the recruitment cessation and will ask them to provide information on how many letters they sent out and how many expressions of interest they received.

**b) Assessments for families already participating in the study (end-point and follow-up assessments)**

- Three of the assessments were conducted virtually via Microsoft Teams between 09/12/2020 and 12/01/2021.
- Since 12/01/2021 all the assessments have been conducted virtually via Microsoft Teams.
- The content and structure of the assessments remain the same. The blank equipment and blank forms are sent to parents via post. No identifying information appears on any of the forms.

**c) Therapy sessions**

- Three of the weekly sessions were conducted virtually via Microsoft Teams between 03/11/2020 and 12/01/2021.
- Twenty of the fortnightly sessions were conducted virtually via Microsoft Teams between 03/11/2020 and 12/01/2021.
- Since 12/01/2021 all the assessments have been conducted virtually via Microsoft Teams.
- The content and structure of the assessments remain the same. The visual materials are sent to parents via post. No identifying information appears on any of the forms.