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Children with autism who understand more than they can say: Can training motor skills help develop communication without speech?

Submission date
11/03/2019

Recruitment status
No longer recruiting

Registration date
12/03/2019

Overall study status
Completed

Last Edited
09/11/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many people talk about autism, many know someone living with autism, but the science and the public discussion of autism are dominated by that fraction of autistic people who can speak to communicate. Those whose autism is more severe are all too often overlooked: they are excluded from scientific research as unable to comply with experimenters' instructions, and they get short-changed when it comes to community placements and education. They are the most in need of clinical therapeutic and educational interventions, yet they get left out of the picture. In a user-centred design process partnered with autistic clients and their therapists, we have developed Point OutWords (http://PointOutWords.online/) an iPad app-assisted communication training system targeted at this neglected population. Whereas many teaching and learning strategies adapted from methods for non-autistic people end up working against autistic cognition by asking people with autism to do what they cannot easily do, Point OutWords works with autistic individuals and their caregivers: Beginning from the cognitive strength of perceiving localised details, caregivers model and develop skills in manipulating puzzles, then build up to pointing at letters on a keyboard. Having shown improvements in visuomotor and language skills in a pilot project with autistic schoolchildren, we now will test Point OutWords in an NHS setting: working with patients, families and clinicians throughout, this feasibility project will evaluate our ability to recruit and to retain families in sufficient numbers, families' ability to accept and to use Point OutWords as recommended, and the practicality for families and utility in controlled-trial outcome measurement of several tests that could be used to measure improvements produced by Point OutWords. Findings will be shared with the autism community through organisations and publications, and will be used to design a subsequent, larger trial in cooperation with autism families.

Who can participate?
Children aged 3-15 years with a diagnosis of autism who have impaired motor skills, are able to understand more than they can speak and are patients of the NHS Peterborough Neurodevelopmental Service can take part in the study with their parents.

What does the study involve?
Children are allocated to one of two groups; intervention or control. The children in the intervention group will receive the Point OutWords intervention for half an hour a day, 5 days a week for 8 weeks along with usual NHS therapy. The intervention involves practising visuomotor and sequencing skills which serve as building blocks for social development and language acquisition. Those in the control group receive therapy as usual and use other iPad apps so that both groups spend comparable amounts of time engaged with a caregiver on iPad-based activities.

Children and parents are assessed on a range of psychometric tests evaluating motor, language, and communicative skills before and after the intervention and at a three-month follow-up. In addition to psychometric measures, qualitative data (focus groups, "Think Aloud" sessions, diaries) are collected to explore the experience of using Point OutWords within the family routine. Internal data logged in the app are collected such as changes in speed and accuracy of movement over the course of the intervention.

What are the possible benefits and risks of participating?
Point OutWords was developed to improve communication skills in children with autism and children who take part in this intervention might benefit from the app in this way. However, the app's effectiveness has not been proven: there might not be any benefit at all. Indeed, this is the issue that the current trial aims to explore.
Families assigned to the control group may be dissatisfied and so, the control group will receive the Point OutWords intervention after the trial is completed.
There are no notable risks associated with taking part in this study.

Where is the study run from?
The study is run by Cambridgeshire and Peterborough NHS Foundation Trust with Nottingham Trent University and the University of Cambridge. Participants will be recruited from the CPFT Integrated Children's Service Peterborough and data collection will take place in participants' homes in and around Peterborough (UK).

When is the study starting and how long is it expected to run for?
March 2019 to March 2020

Who is funding the study?
NIHR Central Commissioning Facility (CCF)

Who is the main contact?
Dr Matthew Belmonte, belmonte@mit.edu

Contact information

Type(s)
Public

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Protocol serial number
40703

Study information

Scientific Title
Evaluation of Point OutWords, a Motor Skills Intervention to Promote Language Development in Non-Verbal Children with Autism: A Feasibility Randomised Controlled Trial.

Study objectives
1. This feasibility trial aims to evaluate children's and families' engagement with an intervention supported by our iPad app, Point OutWords. The study will assess fidelity to the intervention and will determine whether sufficient participants can be recruited for a future full-scale randomised controlled trial.
2. We hypothesise that children with autism spectrum disorder (ASD) in the intervention group will show improvements in language and communication associated with enhanced motor skills contrasted to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2019, Nottingham 2 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 020 7104 8107; NRESCommittee.EastMidlands-Nottingham2@nhs.net), ref: 18/EM/0068

Study design
Single-centre feasibility parallel-groups randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions

Individuals will be randomly allocated to the intervention or control group. Block randomisation, stratified by gender, will be performed in Sealed Envelope (https://www.sealedenvelope.com/), an online software application for randomising patients in clinical trials.

Experimental group: The experimental group will receive at least 20 hours (a half an hour a day 5 times a week for 8 weeks) of the Point OutWords intervention, as an adjunct to standard NHS clinical therapy for nonverbal or minimally verbal autism. The Point OutWords intervention will be administered in the family home. Parents will receive written training materials and telephone follow-ups.

Point OutWords is intended to be used with a parent who can support the autistic client in an 'errorless learning' format, filling in responses and correcting errors when the client is unable to do so independently, and redirecting the client towards the task when their attention wanders. Our iPad app provides motor training of skills prerequisite to communication (pointing) and language (sequencing). We hypothesise that such motor training could evoke gains in communicative skills within a motor-impaired group.

Control group: Individuals not receiving the experimental intervention will receive standard NHS clinical therapy. To control for total contact time with the iPad, the control group will be offered a selection of other apps. These control apps were selected based on the absence of Point OutWords' tasks and skills, such as sequencing, jigsaw puzzles, vocabulary learning, fine motor skill training, social learning, or teaching concepts that underlie language development e.g. category learning. The apps selected were Magic Fluid Lite, Heat Pad, Draw Stars!, BabyDrum, Doodle Buddy, Aquarium Live, and Dogs. The control group will receive equal regular contact and support during the study period, and will be offered Point OutWords intervention after the end of the study period.

Intervention Type
Behavioural

Primary outcome(s)
Child measures:
1. Fine Motor skills, Receptive Language and Expressive Language will be assessed using the Mullen Scales of Early Learning pre-intervention, post-intervention, and at a three-month follow-up.
2. Change in autistic behaviours will be measured using the Brief Observation of Social Communication Change (BOSCC) pre-intervention, post-intervention, and at a three-month follow-up.
3. The social interaction between parent and child is measured using the Dyadic Communication Measure for Autism (DCMA) pre-intervention, post-intervention, and at a three-month follow-up (the BOSCC and the DCMA are scored from the same twelve-minute recording of parent-child play).
4. Receptive language will be assessed using the British Picture Vocabulary Scale (BPVS-3) pre-intervention, post-intervention, and at a three-month follow-up.

Parent checklists :
5. Social communicative competence will be measured by Social Responsiveness Scale (SRS-2) pre-intervention, post-intervention, and at a three-month follow-up.

Assessing feasibility and acceptability:
1. Internal data from the iPad app such as usage time and number of distinct sessions are used to assess fidelity to the intervention regime and are collected during the intervention period.

2. The feasibility and experience of using the app in the context of the daily family life will be explored by asking parents to keep a diary during the intervention period and by holding focus groups after the end of the intervention period.
3. The usability of the app will be explored using two “Think Aloud” sessions conducted during the first and last intervention session where the caregiver will be asked to speak aloud their attitudes towards the app in real time.
4. Acceptability of the intervention to clinicians will be explored through individual interviews after the intervention period.

Key secondary outcome(s))
Child measures:
The Neuromotor integrity of the speech system will be assessed using the Verbal Motor Production Assessment for Children (VMPAC) pre-intervention, post-intervention, and at a 3-month follow-up.

The iPad will record the child’s real-time finger movements when they are using Point OutWords for the duration of the intervention period. Changes in manual motor skills will be measured in the following parameters:
1. Visumotor targeting error is measured as the Euclidean (straight-line) distance between the initial point of contact with the screen and the nearest extent of the target puzzle piece.
2. Motor efficiency is measured as variance of linear speed in the direction of motion and angular speed (the rate of change in direction of motion over time).
3. Accuracy in movement will be measured as a ratio of the actual drag path to the shortest possible path length.

Parent measures:
1. Stress related to the relationship between parent and child will be measured using the Parenting Stress Index (PSI-4) pre-intervention, post-intervention, and at a three-month follow-up.
2. Communication, daily living skills, socialisation, motor skills, and maladaptive behaviour will be measured using the Vineland Adaptive Behaviour Scales (VABS-2), a parent interview pre-intervention, post-intervention, and at a three-month follow-up.
3. Satisfaction with family life will be measured using the Family Quality of Life Scale (FQoL) pre-intervention, post-intervention, and at a three-month follow-up.
4. Change in autistic behaviour will be measured using the Autism Impact Measure (AIM) pre-intervention, post-intervention, and at a three-month follow-up.

Completion date
14/03/2020

Eligibility

Key inclusion criteria
1. Autism diagnosis provided by a detailed clinical history (all of which are obtained as part of routine NHS care).
2. Nonverbal or minimally verbal (lacking communicative speech, or speaking fewer than 100 single words and no phrase speech).
3. Clinical judgement of motor impairment.
4. Receptive language surpasses expressive language.
5. Ages 3 to 15 years old.
6. English is the primary language spoken in the home (as Point OutWords is not yet translated).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
15 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Diagnosed with vision or hearing impairment (which would affect interaction with an iPad).
2. Caregiver does not speak English.
3. Diagnosed with severe impairment of motor function (e.g. cerebral palsy).

Date of first enrolment
13/03/2019

Date of final enrolment
17/01/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
CPFT Integrated Children's Service
Thorpe Road
Peterborough
United Kingdom
PE3 6DB

Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

ROR
https://ror.org/040ch0e11

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20019

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent open-access results publication. The plan is to make these data available as supplementary information alongside the article. In the unlikley event that this is not possible- for example, if the size of the data set were to exceed the journal's limit on supplementary files - then the dataset would be made available separately in a publicly available repository such as Zenodo. All data have been pseudonymised, and this pseudonymisation will be retained when the dataset is made public. The ethics approval and the informed consent of subject families permit this sharing.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/01/2020	27/01/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	methods	09/05/2019		Yes	No
Other publications	clinical methodology	07/04/2021	01/03/2021	Yes	No
Other publications	Lessons learnt from study	07/04/2021	09/11/2022	Yes	No
Participant information sheet		13/11/2018		No	Yes
Poster results			09/11/2022	No	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes