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Can the Pirates game be used to help assess children with possible autism?

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
17/02/2020

Overall study status
Completed

Last Edited
07/06/2023

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
Autistic Spectrum Disorders (ASD) are where a child's brain develops differently, leading to difficulties with social communication and interaction. ASD describes a range of severity, so that some people with ASD do not speak and find unfamiliar situations distressing, while others are able to work and function in society in a more typical way. ASD affect at least 1 in 100 of the population. It is recommended in the UK that diagnosis of ASD requires a mixed team of healthcare and education professionals. Information comes from many settings, including home and school, where evidence of autistic behaviours and/or patterns of thinking can be observed. There are tools available to guide observation of children, such as the Autism Diagnostic Observation Schedule (ADOS), but these tools can take a long time to complete. Research in the UK suggests it takes 13 hours of professional time to complete an assessment. This costs around £800 per child. Most teams use two stages. This includes an initial screening clinic to determine the need for the full multidisciplinary diagnostic assessment. Diagnostic services are under pressure to meet the growing demand. Waiting times can be between 6 months to 2 years to complete an assessment.
This study aims to investigate whether a game played on a tablet can incorporate tests used to detect signs of possible ASD in children. This could be a quick and fun way to identify children who could benefit from more detailed screening for ASD.

Who can participate?
Children aged 5-11 years who have either already been diagnosed with autism or who are developing typically and have not been in contact with a child development team .

What does the study involve?
The app is a pirate adventure game using Lego characters. It is played on a tablet. The children with autism will play the game while at the child development clinic. Typically developing children will play the game at school.

What are the possible benefits and risks of participating?
There are no potential benefits to playing the app, which takes around 10 minutes. The children will be told before they start that if they don't like playing the game, they should tell their parent or teacher. They can stop playing and nobody will be cross with them.

Where is the study run from?
Sussex Community NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2015 to September 2020

Who is funding the study?
British Medical Association Helen Lawson Fund (UK)

Who is the main contact?
Dr William Farr, will.farr@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
217234

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 35758, IRAS 217234

Study information

Scientific Title

Establishing accuracy parameters of a child social communication assessment tool

Study objectives
Autistic Spectrum Disorders (ASD) affect at least 1.1% of the population (CDC, 2014). NICE recommends that diagnosis requires a multidisciplinary team assessment, obtaining information from various settings including home and school, as well as testing for evidence of autistic behaviours and/or patterns of thinking (NICE, 2011). A number of tools have been developed to aid this process including observational tools such as the Autism Diagnostic Observation Schedule (ADOS). This is a lengthy process, our own study of practice in UK suggesting this takes around 13 hours of professional time to complete, costing around £800 per child (Galliver et al., in submission). Most teams (10 of 12) employed a two-stage process including an initial screening clinic determining the need for the full multidisciplinary diagnostic assessment. Diagnostic services are reporting increasing pressure to meet the growing level of demand, frequently resulting in waiting times of between 6 months and 2 years to complete an assessment (Autism Achieve Alliance, 2014).
This study aims to pilot a new digital tool, developed by the research team, which incorporates a number of psychometric tests used in diagnostic assessment. It is in the format of a pirate adventure game, that can be used at the initial assessment alongside history taking, screening questionnaires (e.g. SCQ), and information collected from educational settings. The assessment takes 10 minutes to complete and initial clinical experience suggests it provides useful additional information about the child.
This study will pilot the use of the tool in children attending an initial assessment clinic and in typically developing children attending a local primary school.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/10/2017, London - Hampstead Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester M1 3DZ; +44 (0)2071048127; nrescommittee.london-hampstead@nhs.net), ref: 16/LO/2138

Study design
Non-randomised; Interventional; Design type: Screening, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
See additional files.

Health condition(s) or problem(s) studied

Diagnosis of autistic spectrum disorders (ASD) in children

Interventions

Part 1: Observational study of use in clinic
Parents, and their children who are formally diagnosed with autism spectrum disorder, will be asked if they are willing to take part in the study with information leaflets sent out in advance. If they answer yes, then the research team will play Pirates with the child. This takes about 10 min to complete. In playing Pirates, the child will be asked a series of questions, presented in the game, exploring the child's ability to recognise facial expressions, think what someone else is thinking, recognise sarcasm and the use of a lie and to understand idiom.

The child's answers will be recorded on a scoresheet whilst an observation schedule will be used to record any unusual behaviours, and comments made by the child whilst playing the game. This will be performed on a single occasion as part of the clinic visit.

Parents will also be asked to complete the Social Communication Questionnaire (SCQ) if it was not completed as part of the diagnostic assessment. This is a validated screening tool containing 40 tickbox questions exploring the presence of possible autistic symptoms as reported by the parents. Scores of 15/40 or more indicate the need for formal diagnostic assessment and a score of 22 or more indicates likely ASD (Chandler et al, 2007). Parents already complete the SCQ as part of routine local clinical practice. Parents of those children who had the SCQ completed as part of the diagnostic assessment will be asked within consent to seek permission to access patient notes to obtain results of SCQ, and other formal clinical assessment e.g. ADOS, ADI.

The results of Pirates will be compared with the SCQ score and clinical diagnosis, which is based on formal history from parents e.g. ADI, formal observation of the child in clinic (ADOS), and observation of the child in-school.

Part 2: Testing use in typically developing children (controls) in local mainstream school
Children of primary school age (4-11) attending a local primary school will be assessed in the school setting by the research team. A study pack comprising information sheets (child and parent), consent form, child assent form, and a short parental questionnaire (assessing whether their child has any recognised developmental, communication or learning difficulties) will be sent home with the child. The game will be played in the same way as described above for the 'clinic group', but in the child's school, in sight of their classroom and teacher. Again this will be done on a single occasion, taking about 10 min to complete.

In order to avoid causing upset, or concerns about disability discrimination, children with special needs will be free to take part, and indeed it will be interesting to see how they perform, but their results will not be included as part of the 'typically developing' group. Results will again be recorded using the Pirates scoresheet and observation schedule. Whilst this is not a formal case-control study, we have included the typically developing children to act effectively as a control group, enabling us to determine whether children with no evidence of social communication difficulties perform differently to those where there are concerns.

Intervention Type

Behavioural

Primary outcome measure

1. Number of incorrect responses to questions recorded in the app. These data will be used to calculate sensitivity and specificity of the game in detecting possible autism.

2. Characteristics of ASD in children attending the clinic who have been diagnosed with an ASD assessed using the Social Communication Questionnaire (SCQ)

Secondary outcome measures
Behaviour and comments made by children while paying Pirates recorded on an observation schedule

Overall study start date
01/04/2015

Completion date
30/09/2020

Eligibility

Key inclusion criteria
Part 1:
1. Child of primary school age (i.e. 4-11 years)
2. Confirmed diagnosis of ASD following full multidisciplinary diagnostic assessment by a CDC

Part 2:
3. Child of primary school age (i.e. 4-11 years)
4. No concerns about the child’s social communication, and/or possible ASD. Children with these difficulties may take part in the study but results will not be included within 'typically developing' group analysis.
5. No developmental diagnoses such as learning difficulties, ADHD or Developmental Coordination Disorder. Children with these difficulties may take part in study but results will not be included within 'typically developing' group analysis.

Participant type(s)
Mixed

Age group
Child

Lower age limit
4 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
Planned Sample Size: 124; UK Sample Size: 124

Total final enrolment
110

Key exclusion criteria
Part 1:
1. No concerns about social communication or diagnosis of autistic spectrum disorder
2. Not under care of a CDC.
3. Children who speak English as a second language
4. Non-verbal
5. Severe learning difficulties

Part 2:
6. Children who speak English as a second language
7. Non-verbal
8. Severe learning difficulties

Date of first enrolment
01/06/2018

Date of final enrolment
05/09/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Community NHS Foundation Trust
Brighton General Hospital
Elm Grove
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United Kingdom
BN2 3EW

Sponsor information

Organisation
Sussex Community NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.sussexcommunity.nhs.uk/

ROR
https://ror.org/04e4sh030

Funder(s)

Funder type
Other

Funder Name
British Medical Association

Alternative Name(s)
BMA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
National Institute for Health Research

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2	29/09/2017	17/02/2020	No	Yes
Participant information sheet	version v2	29/09/2017	17/02/2020	No	Yes
Participant information sheet	version v2	29/09/2017	17/02/2020	No	Yes
Participant information sheet	version v2	29/09/2017	17/02/2020	No	Yes
Basic results	version 2	29/09/2017	18/10/2021	No	No
Protocol file			14/10/2022	No	No
HRA research summary			28/06/2023	No	No