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Virtual reality intervention for anxiety in children with ASD

Submission date	Recruitment status	[ ] Prospectively registered
22/04/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/02/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration.

Contact information

Type(s)
Scientific

Contact name
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Newcastle University
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NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18461

Study information

Scientific Title
Reducing anxiety in children with autism spectrum disorders through virtual reality environments

Study objectives
The aim of this study is to investigate whether a virtual reality environment is effective at treating specific fears/phobias in young people with autism spectrum disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Tyne & Wear South Research Ethics Committee, 15/12/2014, ref: 14/NE/1177

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Children, Mental Health; Subtopic: All Diagnoses, Anxiety, Autism spectrum disorders; Disease: Anxiety, Autism spectrum disorders, All Diseases

Interventions
Virtual reality: Computer generated images of the phobia/fear that a child with ASD has.
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Primary outcome measure
Reduction in anxiety and improvement in functional behaviour; Timepoint(s): 2 weeks after intervention, 6 months after intervention and 12 months after intervention

Secondary outcome measures

N/A

Overall study start date
01/03/2015

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Children aged 8-14 years old, boys and girls, with a diagnosis of autism, ASD or Asperger's syndrome
2. Learning ability/IQ estimated to be within the average range
3. Fluent verbal skills; having situation specific anxiety
4. Parent/carer and young person willing to attend sessions at the VRE
Target Gender: Male & Female; Upper Age Limit 14 years ; Lower Age Limit 8 years

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
Planned Sample Size: 32; UK Sample Size: 32

Key exclusion criteria
Children without fluent verbal skills due to the need to have sufficient feedback on the use of the VRE. Children unable/unwilling to travel to the VRE. Insufficient English or intellectual ability to understand the forms.

Date of first enrolment
01/03/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Newcastle University
Institute of Neuroscience
Sir James Spence
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Foundation Trust

Sponsor details
St Nicholas Hospital
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3XT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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