

Virtual reality intervention for anxiety in children with ASD

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| Submission date 22/04/2015 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 23/04/2015 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 15/02/2019 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

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

Contact information

Type(s)
Scientific

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United Kingdom
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 |