ISRCTN58483069 https://doi.org/10.1186/ISRCTN58483069

Using a virtual reality environment to reduce anxiety in children with autism spectrum disorders

Submission date
03/02/2014

Recruitment status
No longer recruiting

Registration date
04/03/2014

Overall study status
Completed

Last Edited
24/02/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many children with autism spectrum disorders (ASD) show anxiety in response to particular settings. Anxiety is problematic for children with ASD, their peers, parents and teachers, as it causes distress and limits opportunities to participate in activities and learning. Furthermore, the rigid ways of thinking characteristic of ASD mean that therapy for such problems requires some adaptions. This study will investigate one such adaption, the use of a virtual reality environment, combined with traditional therapy, to reduce anxiety in children with ASD.

Who can participate?
We will recruit children aged 8-14 years with fluent verbal skills and a diagnosis of ASD, autism or Asperger's syndrome.

What does the study involve?
Assessments will be carried out before the start of the study and an individualised programme of therapy is designed for each child. Their specific anxiety-provoking situation can be reproduced in a virtual reality facility known as the Blue Room. With support from a psychologist and training in coping strategies, children will be gradually introduced to their 'trigger' situation in the blue room environment. After 2-4 sessions in the virtual environment, they will be reintroduced to the real life environment that causes anxiety. Anxiety will be assessed before and after treatment using questionnaires and interviews. In addition, we will be testing the use of a physiological measure of anxiety. This will be via a wristband device and will measure galvanic skin response, which gives a measure of the level of anxiety experienced.

What are the possible benefits and risks of participating?
The benefits to taking part are that your childs anxiety to a specific situation may be reduced. There are no risks associated.

Where is the study run from?
Newcastle University, UK.

When is the study starting and how long is it expected to run for?
The study started in March 2012 and ran until March 2013.

Who is funding the study?
Newcastle University, Daphne Jackson Fellowship

Who is the main contact?
Dr Morag Maskey
morag.maskey@ncl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Jeremy Parr

Contact details
Institute of Neuroscience
Level 3
Sir James Spence Institute
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

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

Study objectives
1. This is an initial investigation into whether we can use a virtual reality room to recreate specific situations that children with autism spectrum disorder become anxious about.
2. To trial the use of a virtual reality (VR) environment as part of an anxiety treatment

programme in young people with autism spectrum disorder (ASD).
3. Does using a VR environment as part of a treatment programme, reduce anxiety in children with ASD?

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Service NRES Committee North East-Sunderland, 16/03/2012, ref. 12/NE/0018

Study design
Pre and post study design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Autism spectrum disorders (ASDs)

Interventions
At baseline, there will be two meetings with families. First, a member of the research team will meet with the family at home to ensure that they have a clear understanding of what is involved and to answer questions. If the family want to join the study, consent will be obtained at this meeting or seven days thereafter, if they require further time to discuss it. Anxiety questionnaires will also be completed at this point. The meeting will last approximately 1 hour.

There will be a second meeting in the child's home with a clinical psychologist and research associate. This meeting will be a clinical assessment of the child's anxiety in order to select a target that might be addressed therapeutically. This meeting will last approximately 45 minutes.

The child will then receive four sessions in the VRE. Each session lasts approximately 30 minutes and we will undertake 2 sessions in one visit to the VRE location (with a rest gap in between) - with several days in between visits. The sessions will be carefully planned so that the child experiences a feeling of coping and mastery. They will be taught coping self statements and relaxation techniques by a psychologist, both before the session starts and in between sessions.

Before and after each session children will be asked to rate their confidence at tackling their target situation. Parents will watch the session via video link and be asked to rate their child's

confidence using the same scale. Each child will also wear a wristband device while in the Blue Room, which measures galvanic skin response and can be used to monitor their levels of anxiety.

The final session will be real life exposure to the situation we have been working with, supported by the psychologist. The outcome measures will be the same (GSR, confidence ratings).

Six weeks after treatment we will visit the families and repeat the anxiety questionnaires and get an update on real life progress (session of approximately 30 minutes). We will also repeat the questionnaires and updates by telephone at six months and one year after treatment.

Intervention Type
Behavioural

Primary outcome measure
1. Real life improvement measured at 6 weeks, 6 months and 1 year after intervention
2. Change in the Spence child anxiety scale measured at 6 weeks, 6 months and 1 year after intervention
3. Reduction in GSR readings from beginning to end of sessions
4. Change in participants rating of their confidence levels at tackling their target situation on a scale from 6 (very confident) to 0 (not confident)

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/03/2012

Completion date
01/03/2013

Eligibility

Key inclusion criteria
1. Boys and girls aged 8-14 years old
2. Diagnosis of autism, ASD or Asperger's syndrome
3. Learning ability/IQ estimated to be within the average range
4. Fluent verbal skills
5. Having situation specific anxiety
6. Parent/carer and young person willing to attend sessions in the VRE in Durham

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Children without fluent verbal skills due to the need to have sufficient feedback on the use of the VRE
2. Children unable/unwilling to travel to the VRE in Durham
3. Insufficient English to understand the forms
4. Children with a co-morbid disorder e.g. depression, severe conduct disorder, severe generalised anxiety disorder

Date of first enrolment
01/03/2012

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle University (UK)

Sponsor details
Sir James Spence Institute
Level 3
Royal Victoria Infirmary

Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
University/education

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
University/education

Funder Name
Newcastle University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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	02/07/2014		Yes	No