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Investigating the feasibility of virtual reality cognitive behaviour therapy for anxiety in autistic young people

Submission date
11/02/2025

Recruitment status
Recruiting

Registration date
28/02/2025

Overall study status
Ongoing

Last Edited
14/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Virtual Reality has been developed as a treatment for a range of mental health disorders as a means to address NHS waiting times. Another area which could benefit from Virtual Reality is developing effective alternative treatments for those who experience difficulty engaging with mainstream talking therapies and therefore require long-term labour-intensive care, including medication, within CAMHS services. Developing such alternatives would both reduce the financial impact on NHS services, as well as increase the availability of care services thus impacting waiting lists. Typically, this would apply to autistic young people accessing CAMHS services. Social Anxiety Disorder (SAD) has been reported as one of the most common mental health difficulties across the lifespan, with the age of onset in adolescence at approximately 13 years old. Autistic young people demonstrate higher scores on measures of SAD in comparison to neurotypical young people. In terms of prevalence rates, it has been found that 40% of autistic young people experience co-morbid anxiety. Cognitive Behavioural Therapy (CBT) is the first-line treatment for social anxiety. Despite this, it is recognised that CBT requires some adaptations for autistic young people. For instance, it is acknowledged that autistic people may experience difficulties with some core parts of the treatment plan such as imaginal desensitisation. It is also recognised that autistic people may experience difficulties in recognising anxiety as a result of alexithymia. Thus, SAD continues to impact on education and general functioning and increases the risk of other mental health conditions developing. As such, autistic young people continue to require long periods of care through CAMHS, as well as building a reliance on medication. Typically, autistic young people with anxiety account for approximately 50% of a CAMHS caseload requiring care for over 24 months. In recent years, virtual reality (VR)-based interventions demonstrated potential because of their low cost, a high motivational index for autistic young people, and their faster and more stable improvements. The majority of autistic young people show familiarity with information technology, leading them to have a higher level of involvement and a reduction in problem behaviours in virtual interactions. There is a growing body of evidence that suggests that the use of Virtual Reality to build social skills in the autistic population has led to improvements in emotional recognition, emotion regulation and social skills. Virtual reality has also been used in combination with traditional therapies, such as cognitive behavioural therapy, to improve symptoms related to

specific phobias. There are early studies into the feasibility of Virtual Reality anxiety treatment in adult autistic populations. The technical challenge is harnessing the cognitive-affective-social theory of learning in digital environments for autistic young people and applying this to Virtual Reality treatments for socially anxious autistic young people in a CAMHS clinical setting. Most commercial virtual reality packages are neither theory-based nor clinically tested and are not designed in partnership with psychological therapists within CAMHS. Many interventions on the market are developed with adult populations, rather than developed within the CAMHS community setting. Thus, there is often a mismatch between what therapists within CAMHS require and what is commercially available.
Therefore, this feasibility study set out to design and test a novel intervention within an NHS CAMHS Setting. As this is a newly developed intervention, there will be an initial development phase, where the virtual reality intervention is developed from a research literature review and service user feedback. Once the intervention is developed, recruitment will begin.
The main aim of this feasibility trial will be to inform the development of a subsequent definitive full-scale trial. This feasibility trial will collect information about recruitment, study conduct, delivery, and assessment methods to inform future trial design. Additional qualitative data will be collected from participants to better understand their experience of taking part in a Virtual Reality intervention, their attitudes towards the intervention and the impact on their overall quality of life.

Who can participate?
Community-based patients aged between 12-18 years who have significant autistic traits and anxiety

What does the study involve?
Participants will receive Virtual Reality intervention once a week (50 minutes) for 12 weeks at the CAMHS clinic, in the presence of a support worker.

What are the possible benefits and risks of participating?
The side effect profile associated with the clinical use of Virtual Reality is unclear. There have been reports of Virtual reality making some people feel ill during or after their session. This is called “cybersickness” (motion sickness, involving nausea, dizziness, disorientation, postural instability, fatigue, and eyestrain). The extent to which this occurs is unknown in this treatment, although indications from research are that there are no significant adverse experiences. An appropriate screening tool has been identified to ensure that adverse effects are correctly identified and reported. In the initial screening appointment, participants will be asked to complete the Visually Induced Motion Sickness Susceptibility Questionnaire (VIM SSQ), which has been found to be a good indicator of the likelihood of experiencing adverse effects from Virtual Reality. They will test the Virtual Reality headset during screening and consent procedures. After each Virtual Reality session, participants will complete the Virtual Reality Sickness Questionnaire (VRSQ) that has been used as a measurement index to inform the impact of Virtual Reality. Details of the procedures around this are explained in the research protocol. This has been put in place to minimise risk. It is felt the risks of these side effects are no more than could be encountered through a person’s use of technology (e.g., gaming). The potential benefit of effective treatment development is considered worthwhile, as they have a high motivational index for autistic young people. The majority of autistic young people show familiarity with these approaches. In service user involvement in developing this project, there was a high appetite for the use of Virtual Reality, and many have made use of Virtual Reality personally. The virtual reality paradigm will be designed in collaboration with service users to be as pleasant and non-intrusive an experience as possible.
Travelling into the clinic can be anxiety-provoking for some participants with autism. The researcher will ensure that potential participants are able to manage this before inviting them to

the initial screening so that the Virtual Reality intervention provides the same conditions as what would be considered standard care in their care plan.
It is acknowledged that completing Virtual Reality anxiety intervention is a different paradigm to gaming. As with therapy, there can be times that participants become distressed or experience discomfort. Therefore, an appropriate clinician will be present (e.g., assistant psychologist, support worker, or specialist psychiatry trainee) to ensure this discomfort is responded to appropriately within the therapeutic context. Participants will also be informed that they can discontinue at any time. It will also be made clear to participants that they are not obligated to complete any parts of the interventions that they feel are unmanageable or any questionnaires they feel uncomfortable answering. It is thought that this risk is not above the level of risk and discomfort that will be experienced through accessing therapy or standard care through the clinic. Throughout the intervention participants will be monitored for signs of distress and debriefed and will be aware that they can access a review of care and continued support through the clinic care coordinator.
Given the factors above and the feasibility stage of research, this was set up as a pilot study with no randomisation.
Participants can choose to take part in the study or can continue with the standard care being offered in their care plan. Should they take part in the trial and not experience an improvement in anxiety, they will be offered ongoing care within the clinic so as not to impact their offer of care from the service.
Similarly, recruitment was focused within the clinic where researchers are based with care coordinators. This ensures there will be good communication with care coordinators, which will support the management of care and any adverse events. It will also ensure minimal personal data is shared in considering potential participants, as conversations can be held within the clinic setting. It also ensures that the intervention offered will represent standard care offered in the clinic as far as possible. It is thought that this will also reduce the potential for participants to feel undue influence, as they will be choosing one of the care options available to them within the clinic.

Where is the study run from?
Community CAMHS clinic (UK)

When is the study starting and how long is it expected to run for?
December 2023 to December 2025

Who is funding the study?
1. Innovate UK
2. Hertfordshire Partnership University Foundation NHS Trust (UK)
3. Syncvr Medical UK Ltd

Who is the main contact?
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Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
347075

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 62006, Grant Code 10107909

Study information

Scientific Title
The feasibility and acceptability of delivering virtual reality cognitive behaviour therapy for anxiety experienced by autistic young people

Study objectives
The main aim of this feasibility trial will be to inform the development of a subsequent definitive full-scale trial. This feasibility trial will collect information about recruitment, study conduct, delivery, and assessment methods to inform future trial design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/01/2025, Frenchay REC (Ground Floor, Temple Quay House, Health Research Authority, BS1 6PN, UK; +44 (0)207 1048106; frenchay.rec@hra.nhs.uk), ref: 24/SW/0132

Study design
Non-randomized; Interventional; Design type: Treatment, Psychological & Behavioural

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 to request a patient information sheet

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

Interventions
This is a feasibility study, due to the novel intervention, it is an initial development and feasibility investigation. Due to the feasibility stage, it will have a limited sample size (10-25 participants).

As this is a newly developed intervention, there will be an initial development phase, where the virtual reality intervention is developed from a research literature review and service user feedback.

Once the intervention is developed, recruitment will begin. As it is a novel intervention, the focus is on pre- and post-intervention testing, with no double-blind or control group. Participants will be community-based patients aged between 12-18 years who have significant autistic traits as assessed by the Autism Quotient (AQ) questionnaire and significant anxiety as assessed by the Anxiety Scale for Children with ASD (ASC-ASD) and the Liebowitz Social Anxiety Scale (LSAS) for Children and Adolescents.

TRIAL SETTING & RECRUITMENT
The trial will be conducted at one centre, CAMHS North (Saffron Ground, HPFT, Stevenage) with clinicians with experience in assessing mental health difficulties in autistic young people.

Participants will be identified for screening from initial assessments at these clinics, which are part of their routine care. Participants will not be recruited into the study through assertive outreach. The trial will be offered Virtual Reality intervention for anxiety as part of the care options for the clinics.

The research team are located in the clinic, so the referrals can be made in person to the research team. The research team will regularly update the clinics via team meetings to encourage referrals.

In considering current referral rates and reasons for referrals, it is estimated that there will be 15 eligible referrals per month. At this stage, it is unknown what recruitment rates will be, however, within the autistic population there have been requests and interest in virtual reality treatment. Recruitment will also be limited by the number of headsets available, which is 10, as only 10 participants can be actively engaged at one time.

Participant identification
Consent for referral will be gained by the referring clinician and recorded in the medical records,

including how they consent to be contacted (e.g. by phone or by the research assistant joining a routine appointment). A member of the research team will identify participants who have been referred and will complete a screening log. The research assistant will then make contact with the patient to provide further information, this could include joining a routine appointment in the clinic in a friendly manner. After having at least 24 hours for consideration potentially willing patients will be invited to attend the clinic by the research assistant and will be asked to give written consent to undergo screening. Patients will then undergo a screening assessment.

Screening
Patients will consent to be screened for the study. Initially a member of the research team will assess the eligibility through interview and completing the required measures; Autism Quotient (AQ), Anxiety Scale for Children with ASD (ASC-ASD) and the Liebowitz Social Anxiety Scale (LSAS) for Children and Adolescents (if not already completed by the referring clinician). These assessment measures have been selected as those with appropriate norms and reliability with autistic young people.

They will also complete the Visually Induced Motion Sickness Susceptibility Questionnaire (VIM SSQ), which has been found to be a good indicator of the likelihood of experiencing adverse effects from Virtual Reality. Participants who score more than one standard deviation above the mean total score will be advised not to take part in the study (Mean Score Females, 29.23 Standard Deviation 19.05; Mean Score Males 11.36, Standard Deviation 7.76). Once this measure has been completed, should the participant score below threshold, they will be given a brief introduction to the Virtual Reality Headset and an opportunity to test this. After this, they will complete the Virtual Reality Sickness Questionnaire (VRSQ) that has been used as a measurement index to inform the impact of Virtual Reality. There are no 'cut-offs' it is used as an informative index. Should this indicate an adverse reaction they will be advised not to participate in the trial. These measures of virtual reality side effects have been selected from those commonly used in research as appropriate indicators.

The results of all screening will be recorded both in the patients' medical notes and on the research file.

INTERVENTION
Participants will then receive Virtual Reality intervention once a week (50 minutes) for 12 weeks:
• Patients will attend the clinic on the day and time of their appointment
• Patients will be collected from the waiting room by the research assistant who will supervise the intervention.
• They will be taken to a clinic room where they will complete the relevant monitoring questionnaires.
• The intervention will then be delivered. This will be a combination of relaxation skills training and graded exposure via Virtual Reality.
• Relevant screening and measures will then be carried out.
• Homework will be set
• The date and time for the next intervention will then be confirmed.

Participants will be evaluated at baseline, at session 4, session, 8, and session 12 using the assessments measures ASC-ASD & LSAS. Patients will also be asked to identify their goal for therapy and rate on a scale (1-10, 10 being best) how close they feel to achieving this goal at the beginning and end of the intervention.

After every Virtual Reality Intervention session, they will complete the Virtual Reality Sickness Questionnaire (VRSQ) that has been used as a measurement index to inform the impact of

Virtual Reality. There are no 'cut-offs' it is used as an informative index. This will inform recording and monitoring of adverse events, and continuation of the participant in the trial. These measures of virtual reality side effects have been selected from those commonly used in research as appropriate indicators.

In between sessions they will take the headsets home, to enable them to complete practice as homework. When taking the headset home for homework, they will be given instructions on the frequency of use. They will be given the VRSQ to take home and advised to discontinue use if they start to experience symptoms. This will then be reviewed on returning to the clinic.

Participants will then be followed up at 3 months, completing assessment measures. Follow-up after 3 months will be conducted via telephone or in-person (depending on participant preference). The clinic team will then be informed of outcomes, so they can make a decision regarding clinical care. Participants will be entitled to continuation of care by the clinical team as is appropriate to their presentation following the intervention, following the routine care procedures of the clinic.

Any reported adverse events will be followed up by the research assistant by phone, if deemed necessary the patient may be asked to come back to the clinic.

Patients will be required to keep their current psychiatric medication dose stable and not to initiate cognitive behaviour therapy during the 12 weeks of the study. This is to avoid any effect of change in treatment being recognised as a change resulting from the treatment provided in the study. should these restrictions prove unacceptable or a change in treatment is required for a clinical reason the patient will be withdrawn from the study but can continue with the Virtual Reality (if appropriate).

Due to the nature of the intervention, the research-led assessments will not be blinded to the intervention. It is acknowledged that this introduces potential for 'researcher effects' and 'researcher bias'. However, due to the nature of virtual reality and feasibility stage at this stage there are no further controls available.

Qualitative feedback will be gathered from participants using a weekly feedback form and a patient experience questionnaire at the end of treatment. Therapists will also be asked to complete a feedback form at the end of treatment.

Should patients opt to discontinue the study at any point after providing consent, they will be offered an exit interview to discuss their experiences and motives for discontinuation with the research assistant.

PAYMENT

There is no financial reimbursement associated with the travel or time commitment to the study as it forms part of routine care, for which no reimbursement is paid. Those entitled to travel claims due to universal credit will be able to claim these through the clinic as part of routine care.

WITHDRAWAL CRITERIA

Willingness to take part in the study will be confirmed with the patient at the beginning of each intervention session, the patient may withdraw from the study at any point. The research clinician will also check that the patient remains eligible for the study for the duration of the time that they are a participant. Should a patient become ineligible they will be withdrawn from the study. Furthermore, if a patient reports any serious adverse experiences they will be withdrawn from the study.

END OF TRIAL
The end of the trial will be defined as the date that the last patient has their 3-month follow-up and clinical review. Follow up after 3 months will be conducted via telephone or in-person (depending on participant preference). The patient will be asked to complete the Anxiety Scale for Children with ASD (ASC-ASD) and Liebowitz Social Anxiety Scale. This can be completed in person or verbally on the phone.

If the patient scores on both of these measures are below the cut-off (a total score of 20 or above on the Anxiety Scale for Children with ASD, ASC-ASD, and a score of 30 or above on the Liebowitz Social Anxiety Scale) then the VR will be considered effective treatment and that it is not necessary for standard care to be offered.

If the patient scores are above the cut-off on either (or both) of the measures then it will be considered necessary to offer standard care. First line of treatment for anxiety is usually CBT. The young person will therefore be allocated for treatment and if a wait-list is identified, will be prioritized for allocation according to their original referral date. This way we can ensure young people will not be disadvantaged due to taking part in this study.

ANALYSIS
The study is designed to evaluate the feasibility of virtual reality intervention, with a limited sample size (10-25 participants). The primary aims described above are focused on the feasibility and acceptability of delivering the intervention, and the associated analysis will be descriptive. There will be no planned interim reports. The analysis will be completed when the trial period ends or sufficient participants have been recruited (whichever is soonest).

Qualitative Analysis
No formal analysis will be completed, nor any quotes will be used from our qualitative data. Data collected from weekly and end of treatment service user and therapist feedback will be summarised and detailed using descriptions (e.g mean, standard deviation)

TIMETABLE
The grant funding for the feasibility is given as 6 months' costings for the Virtual Reality Intervention phase. Development and follow-up will occur outside of this. The development stage will occur before the intervention phase in April – May 2024. During this period, clinical staff will also be informed of the research so they are prepared to start recruiting in June 2024. It is envisaged that there will then be 6 months of intervention testing until December 2024, this takes into account the time to recruit and a limit of 10 headsets. The will then be a 3-month follow-up period after December for the last recruits, this will be January - March 2025. The findings will then be analysed in April 2025, with a final report prepared May – June 2025.

SERVICE USER ENGAGEMENT
Service user engagement was sought in developing the intervention plan, and the exercises and exposure scenarios have been informed by their feedback. The consent forms and information leaflets have also been revised following their feedback.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Virtual reality headset

Primary outcome measure
The primary aim of this study is to establish the feasibility of a future trial using the following outcome measures:
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 6 months
2. Recruitment rate considered by the number of referrals per professional group will also be collated over 6 months.
3. Attrition rate using the number of participants who consent to participate who remain in the study until the end of follow-up at 12 months
4. Ascertainment ratio using the flow of patients through the study from identification to completion over 12 months
5. Session completeness as recorded by session attendance (no. of missed sessions) and homework completion over 12 months
6. Tolerability as measured by the number and nature of adverse events, including ratings on the Simulator Sickness Questionnaire over 12 months

Secondary outcome measures
1. Positive experience as measured by Likert scale ratings of sessions over 12 months
2. Appropriateness of outcomes measures as considered by consistency with ratings of goals over 12 months

Overall study start date
01/12/2023

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Community-based service users, aged 12-18 years
2. Significant autistic traits as assessed by a score of 32-50 on the Autism Quotient (AQ) questionnaire (indicates a strong likelihood of ASD)
3. Significant anxiety as assessed by a total score of 20 or above on the Anxiety Scale for Children with ASD (ASC-ASD) and a score of 30 or above on the Liebowitz Social Anxiety Scale (30-49 indicates mild social anxiety)
4. Ongoing medication (SSRI, tricyclic antidepressant, antipsychotic, benzodiazepine) is allowed as long as the dose is kept stable for a sustained period before (>=6 weeks)

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Score on the Visually Induced Motion Sickness Susceptibility Questionnaire (VIM SSQ), that is one standard deviation above the mean total score will be advised not to take part in the study (Mean Score Females, 29.23 Standard Deviation 19.05; Mean Score Males 11.36, Standard Deviation 7.76)
2. History of psychotic disorder (psychotic symptoms, bipolar disorder)
3. Alcohol/substance abuse disorders within the past 12 months
4. Any other DSM-5 disorder that is considered the primary focus of treatment
5. Actively planning suicide as judged by the clinician to be at significant risk of acts of suicide
6. Received Virtual Reality Treatment in the last 6 months
7. CBT is not allowed during or within 6 weeks of the start of the intervention
8. Regular psychotropic drugs use other than permitted medication
9. Currently involved in a treatment research study
10. Epilepsy or other clinically defined neurological disorder or insult
11. Currently receiving specialist care for any vision-related difficulties (e.g. double vision)
12. Experience of severe migraines
13. Inadequate understanding of English to give informed consent or such that the outcome measurement is not possible

Date of first enrolment
01/05/2025

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield

United Kingdom
AL10 8YE

Sponsor information

Organisation
Hertfordshire Partnership University NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.hpft.nhs.uk/

ROR
https://ror.org/0128dmh12

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Hertfordshire Partnership University Foundation NHS Trust

Funder Name
Syncvr Medical UK Ltd

Results and Publications

Publication and dissemination plan
Planned publication of protocol and results

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. Data will be held in NHS files with a dedicated research centre folder and site files within MSteams on a protected NHS network. This will include Excel spreadsheets of data. Data will be anonymised within case report files, with research identifiers. Only members of the research team will have access to the research folders within MSteams. As this is a feasibility study, there is no data analysis and no data will be shared. The collection of data will be a guide to the feasibility of the measures and intervention.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available