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Virtual Reality for Visions (VRV)

Submission date 29/04/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/05/2025	**Overall study status** Completed	
Last Edited 01/06/2026	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Visions are the experience of seeing things that other people cannot. Up to two-thirds of people with Psychosis report visions. Psychosis is a term for several conditions where people are distressed by seeing, hearing, or believing things that other people do not. Currently, there are no proven treatments to help people deal with their visions. This programme aims to develop and test a new treatment in which an experienced therapist helps people understand what can cause visions, that other people have similar experiences and that they do not need to be afraid. The person then learns to manage their visions differently using virtual reality. This helps the person build the confidence to try different ways of managing their visions. The main goal is to reduce the distress and impact of the visions. This study has been developed with people with lived experience. A lived experience advisory panel will be involved in all aspects of the project. Two co-applicants with lived experience of visions, psychosis and using mental health services will support the study and the public and patient involvement element of the research.

Who can participate?
People with visions attending psychosis services

What does the study involve?
Participants will be asked to come to 4-6 sessions that help explain why people have visions and introduce new coping strategies to manage visions. They will have 4-6 sessions of virtual reality therapy, and complete assessments before the therapy sessions start, halfway through therapy (6 weeks), and after therapy has finished (12 weeks and 16 weeks). The research team will also undertake in-depth interviews to help understand how to improve the treatment.

What are the possible benefits and risks of participating?
The main benefit for participants is the knowledge that they are taking part in research that is likely to help improve the care that is provided to people with visual hallucinations.

There is a potential risk that they may find it distressing to answer the researchers' questions during your appointments with them. It is fine to take a break or stop the session if this occurs. The treatment itself could cause some anxiety as participants will be discussing their experiences of seeing things, and then the VR will provide a representation of the visual hallucination. They may find this upsetting. Most people do not find VR upsetting, but some can feel dizzy or a bit tired afterwards. There will be a therapist with them at all times. Participants

can ask the team to stop showing the image of the vision, and they can spend time before and after each session helping them feel more at ease. Family or friends can join them for the sessions as well.

Where is the study run from?
Gateshead Early Intervention in Psychosis service, UK

When is the study starting and how long is it expected to run for?
November 2024 to October 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK

Who is the main contact?
Dr Rob Dudley, rob.dudley@cntw.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
330558

Central Portfolio Management System (CPMS)
56943

National Institute for Health and Care Research (NIHR)
206602

Study information

Scientific Title
Virtual Reality for Visions (VRV): A proof-of-concept study examining the development of a new treatment for distressing visual hallucinations in people with psychosis.

Study objectives
Visions are the experience of seeing things that other people cannot. Up to two-thirds of people with Psychosis report visions. Psychosis is a term for several conditions where people are distressed by seeing, hearing, or believing things that other people do not. People with visions tell us that they:
1. Don't understand why they see them,
2. Feel different from others,
3. Find these experiences to be frightening,
4. Find it hard to manage everyday activities.

Currently, there are no proven treatments to help people deal with their visions.

The research team want to develop and test a new treatment in which an experienced therapist helps people understand what can cause visions, that other people have similar experiences and that they do not need to be afraid. The person then learns to manage their visions differently using virtual reality. This helps the person build the confidence to try different ways of managing their visions.

To test it, this study will ask 16 people with vision hallucinations attending psychosis services to:
1. Come to 4-6 sessions that help explain why people have visions and introduce new coping strategies to manage visions,
2. Have 4-6 sessions of virtual reality therapy,
3. Complete assessments before the therapy sessions start, halfway through therapy (6 weeks), and after therapy has finished (12 weeks and 16 weeks).

The main goal is to reduce the distress and impact of the visions. In-depth interviews will also be conducted to help understand how to improve the treatment.

This study has been developed with people with lived experience. A lived experience advisory panel will be involved in all aspects of the project. Two co-applicants with lived experience of visions, psychosis and using mental health services will support the study and the public and patient involvement element of the research.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/05/2025, East Midlands - Leicester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8193; leicestersouth.rec@hra.nhs.uk), ref: 25/EM/0077

Primary study design
Interventional

Study design
Non-randomized proof-of-concept study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Virtual reality treatment for people with lived experience of visual hallucination

Interventions
To achieve these aims, there are three work-streams which map onto our three main objectives. At the heart of this study is the focus on developing a novel and powerful intervention. The MRC guidelines for complex intervention in development recommend the use of Programme theory in treatment development. Programme theory "describes how an intervention is expected to lead to its effects and under what conditions. It articulates the key components of the intervention and how they interact, the mechanisms of the intervention, the features of the context that are expected to influence those mechanisms, and how those mechanisms might influence the context. Best practice is to develop programme theory at the beginning of the research project with involvement of diverse stakeholders, based on evidence and theory from relevant fields, and to refine it during successive phases. A refined programme theory is an important evaluation outcome and is the principal aim when a theory-based perspective is taken. Improved programme theory helps inform transferability of interventions across settings and helps produce evidence and understanding that is useful to decision makers".

The treatment development is aligned with the logic model of O'Cathain et al. The principles guide our work on the current study. In terms of actions, a plan has been identified for the development of treatments for visual hallucinations (VH), and it has already been identified that VH are important, and have brought together a team with relevant experience. The team consists of people with lived experience of visions, researchers, and clinicians. The published evidence has been reviewed, and the research has drawn on existing theories and models to better understand how to help VH. The key tasks are to involve the key stakeholders, to understand the context, attend to future implementation, design and refine the treatment and collect preliminary data. Our three phases map onto these actions.

Phase One will develop, refine and optimise the new treatment for VH. This will be led by and involve people with experience of psychosis and visions. To this end, there are advisory groups with people with VH asking about their experiences of VH to help ensure key features of VH are appropriately and sensitively identified for the assessment phase of the study. The research team will work with the PPI group to establish the best methods to identify and ask about the important characteristics of the vision. The team will review the VUSE package, considering issues such as acceptability and presentation of the content. They will develop examples of the VR environments and run workshops with people with lived experience of visions. This will help ensure VRV is immersive, easy to use, engaging and acceptable. The patient advisory groups are anticipated to run on two to three occasions (so groups of 3-5 people in each session) to ensure people have a chance to use the VR and an opportunity to contribute in smaller group discussions. These groups will be led by our co-PPI lead.

Phase two addresses the feasibility of delivery and uncertainties about the intervention itself by using a case series to explore the impact and experience of our novel treatment. There are three key components of the treatment that involve a) asking about the vision so that a VR representation of it can be constructed, b) 4-6 VUSE sessions explaining why people see things, and introducing key coping strategies, and c) 4-6 sessions of VRV enabling people to practice

these coping skills in the presence of a representation of the vision. The study will assess whether it a) reduces distress associated with VH, b) reduces isolation and stigma associated with VH, and c) improves wellbeing and perceived quality of life.

Phase three concerns future implementation. Early consideration of implementation increases the potential of developing an intervention that can be widely adopted and maintained in real-world settings. Implementation questions will be considered throughout the phases of intervention development, feasibility testing, process, and outcome evaluation.

Phase two research plan (which is the main focus to be considered by the NHS ethics committee)

For the case series, the study will recruit 16 participants meeting eligibility criteria. This is a proof-of-concept study, and the study is to determine the feasibility of developing and delivering a new treatment for VH. However, a case series will help establish the potential benefits of this intervention.

The study will recruit participants from Community treatment teams, or Early Intervention in Psychosis services (according to the inclusion criteria described later). They will be approached by their care team, and if interested, they will be provided a participant information sheet, and then meet a research worker to discuss participation, give consent and undertake a baseline assessment.

Participants will complete measures that ask about VH, depression, anxiety, paranoia, quality of life and functioning. They will complete these measures again midway during the treatment (after about 4-6 sessions, about 6 weeks later) and then again after the 4-6 virtual reality sessions (at about 12 weeks). They will be seen again one more time to see whether any benefits endure at 16 weeks. Assessments will take around 60-90 minutes. Assessments are a combination of self-report questionnaires and semistructured interviews. These meetings can be at a person's home or in a clinic setting. At the 12-week meeting, participants will be asked to complete a questionnaire asking about satisfaction with therapy and the quality of the working relationship with the therapist.

All participants will be offered the chance of treatment. It is not a randomised controlled trial. After the baseline assessment, the person will meet a therapist about a week afterwards. The treatment will be delivered by a qualified, trained and supervised psychological therapist. The person will be seen face to face. The treatment consists of three stages described below.

Description of the VH
The initial session elicits a detailed description of the VH, which will be shared with the VR programmers to allow a representation of the VH to be developed.

VUSE
During the programming time (~3 weeks), the therapist and service user work through the VUSE package over several weekly sessions (-60 min), to understand the causes of VH and foster new skills for their management. The intervention is a novel digital treatment for hallucinations. The treatment draws on the most helpful and valued modules from the MUSE package, and it is currently divided into the following Modules (but will be further developed by the staff and service user treatment development advisory groups):

1. What are Visions? This module provides normalising information about the frequency of visions and the factors that tend to increase visions (for example, substance misuse and sleep deprivation), along with testimonies from other people with visions providing powerful

messages that the person is not alone, and that recovery from or living well with visions is possible.

2. How the Mind Works. This module explains what can lead to people seeing things others do not. It explains how our visual perceptual system can lead to mistaken perceptions, for example, how easily faces are seen in clouds. This places visions in the context of being normal in that they result from a perceptual system that can be put under strain by processes like poor sleep, stress, which increases the risk of making these sorts of mistakes. Key psychological processes such as heightened visual imagery, trauma, expectancy and threat detection are explained with engaging videos and animations. Based on these understandings, targeted coping strategies are introduced

3. Assessment and formulation: Identifying triggers, unhelpful appraisals and coping.
This module takes the information from the first two modules and specifically applies it to the experiences of the individual. It starts by considering whether there are patterns or identifiable triggers/contexts associated with seeing visions. Commonly, they are experienced when tired or stressed, often when the person is alone or in the dark. Identifying these triggers can lead to simple changes (like substituting different activities or turning on lights at the time the vision is experienced) that can reduce the frequency or impact of visions. The next key appraisals relate to seeing the vision are elicited. These may be thoughts of harm to self or others, as the vision represents a real threat. If the person perceives the vision as not real, then they may have fears of losing their mind. Other appraisals are that the visions will persist, or it may be that the content of what people see is distressing. These appraisals and resulting behaviour (leaving the room where they see a vision, trying to look away from the vision) are then linked to more helpful and constructive behaviours, which are identified and practised in preparation for the VR session.

VRV
Following the VUSE sessions, the person attends the VR suite, which is a comfortable environment with a large 180-degree panoramic screen on which the VR VH is displayed. The preference is to use the VR suite, but the option of using a VR headset at their home or team clinical base is also an option that will be discussed with the participant. The person will have 4-6 sessions with the therapist present. The service user is supported in testing the reality of the experience and in helping to change unhelpful appraisals and behaviours in response to the VH. A variety of treatment approaches are feasible within the VR environment. The participant will be supported in testing if the vision is real, perhaps by paying more attention to it and noticing characteristics that challenge whether it is a real phenomenon (such as having unusual features or clothing). Participants may be further encouraged to test if it is real by practising throwing an object at it or trying to photograph it on their phone. Further, using the power of the VR environment, one can practice imagery transformation techniques that are commonly used in working with PTSD or social anxiety to help change the power and intensity of the visual experience (such as changing its size or colour). The sessions will be recorded using video recording equipment in the VR suite. The therapist and participant will review these together after the session to enable the person to consider what they have learnt or done differently in the VR session, and a copy of the video is available to the person to take home and review to help them better manage when they see the vision away from the VR suite.

The therapist will call the participant in between scheduled sessions to check on progress with homework and to check on well-being.

Involvement in the study will be about 16 weeks. Between the end of the treatment at 12 weeks and the follow-up session at about 16 weeks (with an allowance of another 4 weeks if needed),

participants will be invited to share their experiences and thoughts about the treatment using a qualitative interview. This will be undertaken by a researcher trained in interviewing. This will be optional, and another information sheet and consent form will be provided, and informed consent will be taken before undertaking the interview. This can be done in a person's home or in a clinical setting, whichever is preferred for the person. This will take about an hour. The person is reimbursed for any travel expenses to any of the assessment or qualitative interview sessions, and compensated with £20 for each meeting.

At all times, the person will remain open to their clinical team (EIP or CTT). This means that they will continue to have regular visits from a community nurse or care coordinator, have regular medical reviews, and have access to support workers and psychological therapy. Out-of-hours and weekend support is available from the crisis teams if needed.

The case series will recruit 16 people and will be analysed to establish if there are any changes in the frequency, intensity of the VH as well as in the other issues asked about (mood, anxiety, paranoia, quality of life, functioning, etc). This case series design will help determine if there is value in offering VUSE and VR for VH and is appropriate for testing a new treatment approach. If demonstrated to be acceptable and helpful, it will serve as the basis for a future study testing the feasibility of a randomised controlled trial.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
XR/CBT Immersive Studio medical (software) device

Primary outcome(s)
The feasibility and acceptability of VUSE and VR intervention measured using data collected during feedback from patient participants, closely monitoring any changes in the reported frequency, distress and impact on the interviewer-led (PSYRATS VH) and self-report measure of visual hallucinations (Hamilton)

Key secondary outcome(s)
The secondary outcome measures will inform the next step in the research about what the most effective measures are to use in the definitive trial, assessed at pre- and post-treatment (6 and 12 weeks) and follow-up (16 weeks):
1. Distress and disability caused by hallucinations assessed using the (hallucinations) Multi-Modality Unusual Sensory Experiences Questionnaire (MUSEQ) and (MMHM), (paranoia) revised Green et al., Paranoid Thoughts Scale (R-GPTS), and (general distress) General Anxiety Disorder-7 and Patient Health Questionnaire-9 (GAD 7, PHQ-9)
2. Quality of life, stigma and functioning measures collected by the self-report questionnaires: Questionnaire about the Process of Recovery, Internalized Stigma of Mental Illness Scale-9 and Dialogue in Life and Treatment Outcome Goals (QPR, ISMI-9, and DIALOG)
3. Satisfaction with therapy and working alliance will be captured by self-reported measures: Satisfaction with Therapy and Therapist Scale-Revised and Working Alliance Inventory (STTS-R and WAI) at the end of treatment

Completion date

31/10/2026

Eligibility

Key inclusion criteria
1. Aged 16 and above (upper age limit will be determined by the teams recruited from which is usually about 65)
2. Receiving care from Early Intervention in Psychosis services or community treatment teams
3. Meets ICD11 criteria for schizophrenia, schizoaffective disorder or diagnosis of schizophrenia spectrum psychosis (F20-29) or entry criteria for an Early Intervention in Psychosis service
4. Have a history of Visual Hallucinations (VH) for at least three months
5. Would like to receive a psychological intervention specifically for VH
6. Have the capacity to provide written informed consent
7. Be judged by their clinician to be clinically stable for the preceding 4 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any intellectual disability or severe cognitive dysfunction precluding their ability to provide informed consent.
2. Any primary diagnosis of substance misuse dependency or traumatic brain injuries, organic psychoses, or dementia.
3. Unable to use VR (owing to epilepsy, poor eyesight or dizziness).

Date of first enrolment
04/07/2025

Date of final enrolment
28/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Sponsor information

Organisation
Cumbria Northumberland Tyne and Wear NHS Foundation Trust

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/01/2026	14/01/2026	Yes	No