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gameChange VR: automated virtual therapy to help patients with psychosis reduce anxious avoidance of everyday situations

Submission date
28/03/2025

Recruitment status
Recruiting

Registration date
09/04/2025

Overall study status
Ongoing

Last Edited
18/08/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study aims to evaluate gameChange, a virtual reality (VR) treatment for people with psychosis, in real-world settings within the NHS. The goal is to help the National Institute for Health and Care Excellence (NICE) decide whether to fully recommend gameChange for use in the NHS. The project is funded by the National Institute for Health and Social Care Research (NIHR) and supported by the Office for Life Sciences (OLS) and NICE.

Who can participate?
The study will include individuals with psychosis who have severe fears and are often housebound. Participants will be selected from six NHS mental health trusts: Bristol, Cornwall, Humber, Manchester, Oxford, and West Midlands.

What does the study involve?
Participants will be divided into two groups: one group will start using gameChange immediately, while the other group will start after six months. gameChange involves using a VR headset to practice facing everyday situations with the guidance of a virtual therapist and support from mental health staff. Participants will typically have six sessions, but they can have more if needed.

What are the possible benefits and risks of participating?
The potential benefits include a significant reduction in fears related to everyday situations, especially for those with severe problems. This could lead to improved quality of life and greater independence. There are minimal risks, but some participants might find the VR experience challenging or uncomfortable at first.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
March 2025 to October 2027.

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

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
351247

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 67294

Study information

Scientific Title
gameChange VR: a real-world waitlist randomised controlled trial for the treatment of severe agoraphobic avoidance in the context of psychosis

Study objectives
Primary:
For NHS patients diagnosed with psychosis and having severe agoraphobia, gameChange, when added to usual care, compared to usual care, will reduce agoraphobic avoidance (at six months).

Secondary:
1. Compared to usual care, gameChange will reduce agoraphobic avoidance at the end of treatment (8 weeks).
2. Compared to usual care, gameChange will reduce agoraphobic distress.
3. Compared to usual care, gameChange will reduce paranoia.
4. Compared to usual care, gameChange will increase the number of social contacts outside the home.
gameChange is an acceptable treatment for patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/03/2025, Wales REC 3 (Health and Care Research Wales, Castlebridge 4, Cardiff, CF11 9AB, United Kingdom; +44 2920 230457; Wales.REC3@wales.nhs.uk), ref: 25/WA/0081

Study design
Multicentre two-arm waitlist randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home, Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Agoraphobic avoidance (severe) in patients with a diagnosis of psychosis

Interventions
UKCA marked gameChange VR therapy. Guided provision of VR therapy for 8 weeks. Delivery supported by a mental health staff member (e.g, peer support worker, assistant psychologist, therapist). gamechange is a cognitive treatment that aims for patients to relearn safety by testing their fear expectations. Within the VR environments a virtual coach guides the person through the treatment. When first entering VR, the patient goes into the coach's virtual office and is guided in how to use VR. At the beginning of the first session, the virtual coach explains the rationale behind the treatment, and the participant selects one of the six VR scenarios.

The six virtual reality scenarios are: a cafe, GP waiting room, pub, bus, street scene, and newsagent. Each scenario has five degrees of difficulty (e.g, the number and proximity of people in the social situation increases) and participants work their way through each level of difficulty. There are game type tasks within a number of the levels. The participant can choose a different scenario in each session or repeat a previous situation. gameChange is now delivered on a standalone headset.

Control group
The total duration of the study will be 34 weeks. The total duration of treatment will be 8 weeks. The duration of the follow up period in total will be 34 weeks, with assessments at baseline, 8 weeks, 26 weeks, and 34 weeks. After randomisation, the control group will receive their usual care until completion of the 26 week follow up. After this, they will receive gameChange VR therapy (plus treatment as usual) for up to 8 weeks. They will then complete the 34 week follow up, after which participation will be complete. Usual care is typically antipsychotic medication and regular contact with the mental health team.

Treatment group
The total duration of the study will be 26 weeks. The total duration of treatment will be 8 weeks. The duration of the follow-up period in total will be 26 weeks, with assessments at baseline, 8 weeks, and 26 weeks. Usual care will continue.

Randomisation process
Patients will be randomised once they have completed the baseline assessment to either the treatment group or the control group. Randomisation will be carried out by a member of staff

unblinded to treatment allocation. An online system from Sealed Envelopes (https://www.sealedenvelope.com/), will use a permuted blocks algorithm with randomly varying block size, stratified by centre.

Intervention Type
Other

Primary outcome measure
Agoraphobic avoidance is measured using the Oxford Agoraphobic Avoidance (O-AS) – avoidance subscale at baseline, 8 weeks, 26 weeks. (This will be measured additionally at 34 weeks for the wait-list control group i.e. after they have received the treatment.) The primary endpoint for this outcome is 26 weeks.

Secondary outcome measures
1. Agoraphobic avoidance (distress level) is measured using the Oxford Agoraphobic Avoidance Scale (O-AS) – distress subscale at baseline, 8 weeks, and 26 weeks. (This will be additionally measured at 34 weeks for the control group.)
2. Paranoia is measured using the Revised Green et al Paranoid Thoughts Scale at baseline, 8 weeks, and 26 weeks. (This will be additionally measured at 34 weeks for the control group.)
3. Number of social contacts is measured using the Social Contact Assessment at baseline, 8 weeks, and 26 weeks. (This will be additionally measured at 34 weeks for the control group.)
4. Treatment acceptability is measured using the Theoretical Framework of Acceptability (TFA) at 8 weeks for the intervention group. (This will also be measured at 34 weeks for the control group after they have had the VR treatment.)
5. VR side effects will be measured using the Oxford – VR Side Effects Checklist at 8 weeks for the intervention group. (This will also be measured at 34 weeks for the control group after they have had the VR treatment.)
6. Occurrence of serious adverse events will be checked using medical notes (in addition to any patient reports) over 0-26 weeks. (Notes will also be checked for the period 26-34 weeks for the control group.)

Overall study start date
17/03/2025

Completion date
01/10/2027

Eligibility

Key inclusion criteria
1. Attending NHS or commissioned Voluntary, Community and Social Enterprise (VCSE) mental health services.
2. Clinical diagnosis of schizophrenia spectrum psychosis or an affective diagnosis with psychotic symptoms
3. Severe agoraphobic avoidance as assessed by the Oxford Agoraphobic Avoidance Scale (score of 6 or above) and wanting help for that difficulty

Participant type(s)
Patient

Age group

Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Photosensitive epilepsy.
2. In forensic settings or Psychiatric Intensive Care Unit.
3. Command of spoken English inadequate for engaging in the therapy or assessments.
4. A participant may also not enter the trial if there is another factor (for example, current active suicidal plans that need to be the focus of intervention), which, in the judgement of the investigator, would preclude the participant from providing informed consent or from safely engaging with the trial procedures. Reason for exclusion will be recorded.

Date of first enrolment
01/05/2025

Date of final enrolment
01/11/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Health NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
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Oxford
United Kingdom
OX4 4XN

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich

Manchester
United Kingdom
M25 3BL

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Block A, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6FE

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
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BA1 3QE

Study participating centre
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Sponsor type
Research organisation

ROR
https://ror.org/052gg0110

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/06/2028

Individual participant data (IPD) sharing plan
Requests, accompanied by a study summary, for sharing of de-identified data will be considered by the Chief Investigator (daniel.freeman@psy.ox.ac.uk) and the team. The intent is to share data for reasonable requests. Data will be made available to external researchers subject to the constraints of the consent under which data were collected, with an appropriate data sharing agreement, and after publication of the main study report.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/08/2025	18/08/2025	Yes	No