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# The gameChange trial: automated virtual reality therapy to help patients with psychosis feel more confident in everyday situations

**Submission date**
01/05/2019

**Recruitment status**
No longer recruiting

**Registration date**
02/05/2019

**Overall study status**
Completed

**Last Edited**
24/06/2024

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Many patients with psychosis experience everyday social situations as anxiety-provoking. The fears can arise, for example, from paranoia, hallucinations, social anxiety, or negative self-beliefs. The fears lead patients to withdraw from activities, and this isolation leads to a cycle of worsening physical and mental health. Breaking this cycle requires highly active treatment directly in troubling situations so that patients learn that they can safely and confidently enter them. However, patients with psychosis seldom receive such life-changing interventions. To solve this problem researchers have developed an automated psychological treatment delivered in Virtual Reality (VR). It allows patients to experience computer simulations of the situations that they find anxiety-provoking (e.g. a street, a shop, a café, a GP surgery). A virtual coach guides patients, using cognitive techniques, in how to overcome their fears. Patients are willing to enter VR simulations of anxiety-provoking situations because they know the simulations are not real, but the learning made still transfers to the real world. The aim of the study is to test whether the automated VR therapy works (i.e. reduces anxiety and avoidance of social situations).

Who can participate?
Patients with psychosis attending NHS mental health trust services who get anxious in everyday social situations.

What does the study involve?
Participants are randomly allocated to the automated VR cognitive treatment added to treatment as usual, or treatment as usual. The VR treatment comprises about six 30-minute (half an hour) sessions. Assessments are conducted at the start of the study and after 6 and 26 weeks to measure avoidance and distress in real-life situations, psychiatric symptoms, activity levels, and quality of life.

What are the possible benefits and risks of taking part?
It is hoped that the automated VR therapy will enable people to be much more confident about everyday social situations. There are no notable risks of taking part.

Where is the study run from?
Oxford Health NHS Foundation Trust/University of Oxford. There are also trial sites at Bristol, Newcastle, Nottingham, and Manchester (UK)

When is the study starting and how long is it expected to run for?
June 2018 to November 2021

Who is funding the study?
National Institute for Health Research (NIHR), Invention for Innovation programme (i4i) (UK)

Who is the main contact?
Prof. Daniel Freeman
Daniel.freeman@psych.ox.ac.uk

### Study website
https://gamechangevr.com/

# Contact information

### Type(s)
Scientific

### Contact name
Prof Daniel Freeman

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### Contact details
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
2.1

# Study information

## Scientific Title
Automated virtual reality (VR) cognitive therapy for patients with psychosis who have anxious avoidance of social situations: a single-blind parallel group randomised controlled trial (gameChange)

## Acronym
gameChange

## Study objectives
The primary research question we will test is: Does automated VR cognitive treatment (the gameChange VR therapy) added to treatment as usual, compared to treatment as usual alone, lead to a post-treatment reduction in real-world avoidance and distress for patients with psychosis attending NHS mental health services?

The primary hypothesis is that compared to treatment as usual, VR cognitive therapy added to treatment as usual will reduce avoidance and distress of real-world situations (post-treatment).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 29/04/2019, NHS Health Research Authority (HRA) South Central - Oxford B Research Ethics Committee (Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT; Tel: +44 (0)207 104 8168; Email: nrescommittee.southcentral-oxfordb@nhs.net), ref: 19/SC/0075

## Study design
Multicentre parallel-group randomised controlled trial with single-blind assessment

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Clinical diagnosis of schizophrenia spectrum psychosis (F20-29) or an affective diagnosis with psychotic symptoms (F31.2, 31.5, 32.3, 33.3) (ICD-10, WHO, 2010); self-reported difficulties going outside the home primarily due to anxiety

## Interventions

Current interventions as of 31/03/2021:

Participants are randomised (1:1) to the automated VR cognitive treatment added to treatment as usual or treatment as usual.

The gameChange VR treatment is a virtual-reality application recommended for adults (16+) who have anxieties when outside in everyday social situations. This software is intended to reduce anxieties around other people and therefore to help participants feel safer and more comfortable around people. The aim for the outcome is that patients feel more able to go outside into everyday situations. The treatment was programmed by the University of Oxford spin-out company, Oxford VR (www.oxfordvr.org). The treatment is a CE marked Class I Active Medical Device (Standalone Software).

The VR Cognitive Therapy (VRCT/gameChange treatment) aims for patients to test their fear expectations around other people in order to relearn safety. The treatment is not designed as exposure therapy (participants are not asked to remain in situations until anxiety reduces) but as repeated behavioural experiment tests (to learn that they are safer than they had thought). The treatment is designed to be delivered in approximately 6 sessions of thirty minutes. Three sessions will be considered the minimum (adherent) dose of therapy. However, participants can proceed at their own pace, meaning that a fewer or greater number of sessions is allowed. The participant typically stands, and is able to walk a few paces in the scenarios. A virtual coach guides the person through the treatment, including encouraging the dropping of defence behaviours, and elicits feedback to tailor the progression of the treatment. When first entering VR, the patient is guided in a calm VR space how to use VR (i.e. the basic functions). They then go into the coach's virtual office. At the beginning of the first session, the virtual coach explains the rationale behind the treatment, and the participant selects which one of six virtual reality situations that they would like to begin in. The six virtual reality scenarios are a: café, 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. Throughout the sessions, participants' responses to questions from the virtual coach are given by means of gripping a virtual globe. Belief ratings are repeated within VR at the end of each treatment session.

Assessments will be conducted at 0, 6 (post-treatment), and 26 weeks by a researcher blind to allocation. The primary outcome is avoidance and distress in real-life situations, using the Oxford Agoraphobic Avoidance Scale (O-AS, Lambe et al., submitted), at six weeks. The secondary outcomes are psychiatric symptoms, activity levels, and quality of life. Primary analysis will be intention-to-treat. The researchers will also examine how the treatment works. An economic evaluation will be conducted.

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Participants are randomised (1:1) to the automated VR cognitive treatment added to treatment as usual or treatment as usual.

The gameChange VR treatment is a virtual-reality application recommended for adults (16+) who have anxieties when outside in everyday social situations. This software is intended to reduce anxieties around other people and therefore to help participants feel safer and more

comfortable around people. The aim for the outcome is that patients feel more able to go outside into everyday situations. The treatment was programmed by the University of Oxford spin-out company, Oxford VR (www.oxfordvr.org). The treatment is a CE marked Class I Active Medical Device (Standalone Software).

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Assessments will be conducted at 0, 6 (post-treatment), and 26 weeks by a researcher blind to allocation. The primary outcome is avoidance and distress in real-life situations, using a behavioural avoidance task, at six weeks. The secondary outcomes are psychiatric symptoms, activity levels, and quality of life. Primary analysis will be intention-to-treat. The researchers will also examine how the treatment works. An economic evaluation will be conducted.

## Intervention Type
Behavioural

## Primary outcome measure
Because of the pandemic the researchers have not been able to administer the Oxford Behavioural Avoidance Task (O-BAT). They are replacing the O-BAT as the primary outcome measure with the self-report version, which is called the Oxford Agoraphobic Avoidance Scale (O-AS). (added 31/03/2021).

Current primary outcome measure as of 31/03/2021:
Avoidance and distress in real-life situations, measured using Oxford Agoraphobic Avoidance Scale (O-AS) at 0, 6 and 26 weeks (primary outcome timepoint 6 weeks)

Previous primary outcome measure:
Avoidance and distress in real-life situations, measured using Oxford - Behavioural Avoidance Task (O-BAT) at 0, 6 and 26 weeks (primary outcome timepoint 6 weeks)

## Secondary outcome measures

1. Anxious avoidance assessed with the AMI-A (Chambless et al., 1985) and the O-BAT (Freeman et al, 2016) at 0, 6, 26 weeks
2. Activity levels measured by actigraphy at 0, 6, 26 weeks
3. Personal recovery measured with the Questionnaire about the Process of Recovery (QPR) (Neil et al., 2009) at 0, 6, 26 weeks
4. Paranoia measured with the R-GPTS (Green et al, 2008; Freeman et al, in prep) at 0, 6, 26 weeks
5. Worries with paranoid content measured with the Paranoia Worries Questionnaire (Freeman et al, 2019) at 0, 6, 26 weeks
6. Depression measured with the PHQ-9 (Kroenke et al, 2001) at 0, 6, 26 weeks
7. Suicidal ideation measured with the Columbia Scale Severity Scale (Posner et al, 2011) at 0, 6, 26 weeks
8. Meaningful activity measured with the time-budget (Jolley et al, 2006) at 0, 6, 26 weeks
9. Quality of life measured with the EQ-5D-5L (http://www.euroqol.org/) and ReQol (Keetharuth et al, 2018) at 0, 6, 26 weeks
10. Health economics measured with the Client Service Receipt Inventory (Beecham and Knapp, 1992) at 0, 6, 26 weeks

### Overall study start date
01/06/2018

### Completion date
30/11/2021

## Eligibility

### Key inclusion criteria
1. Adults aged 16 years or older
2. Attending a NHS mental health trust for the treatment of psychosis
3. Clinical diagnosis of schizophrenia spectrum psychosis (F20-29) or an affective diagnosis with psychotic symptoms (F31.2, 31.5, 32.3, 33.3) (ICD-10, WHO, 2010)
4. Having self-reported difficulties going outside their home primarily due to anxiety that they would like treated
5. Participant is willing and able to give informed consent for participation in the trial

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
432

### Total final enrolment
346

### Key exclusion criteria

1. Unable to attempt an Oxford-Behavioural Assessment Task (O-BAT) (the primary outcome measure) at baseline (e.g. due to being unpermitted to leave a psychiatric ward)
2. Photosensitive epilepsy
3. Significant visual, auditory, or balance impairment
4. Current receipt of another intensive psychological therapy (or about to start it within the 6-week trial therapy window)
5. Insufficient comprehension of English
6. In forensic settings or Psychiatric Intensive Care Unit (PICU)
7. Organic syndrome
8. Primary diagnosis of alcohol or substance disorder or personality disorder
9. Significant learning disability
10. Current active suicidal plans

(added 31/03/2021) When ethical approval was received on 03/09/2020 to restart the trial following the pause due to COVID-19, this was with a continuing recruitment suspension in place for participants who were at moderate or high risk for a severe course of COVID-19. From 16/02 /2021 patients who were at moderate or high risk for a severe course of COVID-19 could join the trial if they had received the COVID-19 vaccine (subject to medical advice)

### Date of first enrolment
01/07/2019

### Date of final enrolment
07/05/2021

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

### Study participating centre
### Nottinghamshire Healthcare NHS Foundation Trust
The Resource
Trust HQ
Duncan Macmillan House
Porchester Road

Nottingham
United Kingdom
NG3 6AA

**Study participating centre**
**Northumberland, Tyne, and Wear NHS Foundation Trust**
St. Nicholas Hospital
Jubilee Road
Gosforth
Newcastle Upon Tyne
United Kingdom
NE3 3XT

**Study participating centre**
**Avon and Wiltshire Mental Health Partnership NHS Trust**
Jenner House
Avon Way
Langley Park
Chippenham
United Kingdom
SN15 1GG

**Study participating centre**
**Greater Manchester Mental Health NHS Foundation Trust**
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

# Sponsor information

**Organisation**
University of Oxford

**Sponsor details**
Joint Research Office
1st floor, Boundary Brook House
Churchill Drive, Headington
Oxford

England
United Kingdom
OX37LQ
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ctrg@admin.ox.ac.uk

**Sponsor type**
University/education

**Website**
https://researchsupport.admin.ox.ac.uk/ctrg

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Government

**Funder Name**
Invention for Innovation Programme

**Alternative Name(s)**
NIHR Invention for Innovation Programme, i4i

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
The trial protocol will be submitted for publication before the start of the trial. The outcome results, and tests of moderation, mediation, and cost-effectiveness, will be reported in scientific journals and conference presentations.

**Intention to publish date**
01/03/2022

## Individual participant data (IPD) sharing plan

All requests for access to the trial data after the publication of the main outcome data will be considered by the trial team. Please contact Prof. Daniel Freeman (daniel.freeman@psych.ox.ac.uk).

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 27/08/2019 | 30/08/2019 | Yes | No |
| Results article | | 05/04/2022 | 02/09/2022 | Yes | No |
| Results article | Economic analysis | 18/11/2022 | 21/11/2022 | Yes | No |
| Results article | Qualitative results | 16/01/2023 | 17/01/2023 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Protocol article | Automated Virtual Reality Cognitive Therapy for People With Psychosis: Protocol for a Qualitative Investigation Using Peer Research Methods | 25/10/2021 | 24/06/2024 | Yes | No |
| Protocol article | Virtual Reality Cognitive Therapy in Inpatient Psychiatric Wards: Protocol for a Qualitative Investigation of Staff and Patient Views Across Multiple National Health Service Sites | 20/08/2020 | 24/06/2024 | Yes | No |
| Results article | Agoraphobic avoidance in patients with psychosis: Severity and response to automated VR therapy in a secondary analysis of a randomised controlled clinical trial | 01/12/2022 | 24/06/2024 | Yes | No |
| Results article | Virtual reality (VR) therapy for patients with psychosis: satisfaction and side effects | 28/02/2022 | 24/06/2024 | Yes | No |