

# The Phoenix virtual reality self-confidence study

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<b>Registration date</b> 09/06/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/12/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Life can often become challenging for many people diagnosed with mental health difficulties. People's confidence can take a large knock and it can be easy to be self-critical. People's self-esteem can be low. The study team have designed a new Virtual Reality (VR) therapy with the aim of helping people to feel more confident. The VR therapy is called Phoenix. The purpose of this study is to see whether Phoenix is helpful for people. To do this, approximately half the participants will receive the Phoenix VR therapy (in addition to their usual care) and half of the participants will simply continue with their usual care. Whether a person has Phoenix VR therapy is decided by chance. The study team then compare how people who have Phoenix have got on compared to people who have not had Phoenix. Phoenix was designed for people with lived experiences of psychosis. Users enter VR simulations that provide experiences that are designed to help build up positive self-beliefs. There are up to six meetings with a Phoenix staff member. The Phoenix staff member helps support and advise.

### Who can participate?

NHS patients aged 16-30 years old with low levels of positive self-beliefs.

### What does the study involve?

Participants will complete a set of questionnaires at baseline. Participants will then be randomly allocated to one of two groups. The first group will receive Phoenix VR therapy (up to 6 weekly sessions) in addition to their usual care. The second group will continue to receive their usual care. Both groups will then complete another set of questionnaires at approximately 6 weeks and then again at 12 weeks in order to find out if there have been any changes. Whether a person has the Phoenix VR therapy will be randomly decided by a computer (rather like flipping a coin).

### What are the possible benefits and risks of participating?

The study team hope that using virtual reality will help people feel more confident. The study team expect it also to increase psychological wellbeing, and activity levels, and improve mood. The trial aims to find out whether this is the case. There are unlikely to be any significant risks in participating, although occasionally people sometimes may get short-term motion sickness with VR.

Where is the study run from?

1. University of Oxford (UK)
2. Oxford Health NHS Foundation Trust (UK)
3. Berkshire Healthcare NHS Foundation Trust (UK)
4. Northamptonshire Healthcare NHS Foundation Trust (UK)
5. Central and North West London NHS Foundation Trust (specifically teams in the Milton Keynes area) (UK)

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

January 2021 to June 2026. The clinical trial is scheduled to commence enrolment in June 2023 and is expected to conclude data collection in May 2024.

Who is funding the study?

A charity called the International Foundation. The study is also supported by the NIHR Oxford Health Biomedical Research Centre (UK)

Who is the main contact?

Prof. Daniel Freeman  
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## Contact information

### Type(s)

Scientific, Principal investigator

### Contact name

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

312539

### **Protocol serial number**

16125

## **Study information**

### **Scientific Title**

The Phoenix VR self-confidence therapy trial: a randomised controlled trial of automated VR therapy to improve positive self-beliefs and psychological wellbeing in young people diagnosed with psychosis

### **Study objectives**

Our primary hypothesis is that:

1. Compared to treatment as usual, Phoenix VR self-confidence therapy added to treatment as usual will improve levels of positive self-beliefs (end of treatment).

Our secondary hypotheses are:

1. Compared to treatment as usual, Phoenix VR self-confidence therapy added to treatment as usual will improve social comparison and psychological well-being (end of treatment).

2. Compared to treatment as usual, Phoenix VR self-confidence therapy added to treatment as usual will reduce depression, negative self-beliefs, hopelessness, anhedonia, anxiety, and paranoia and increase perceptions of recovery, meaningful activity, and quality of life (end of treatment).

3. Treatment effects will be maintained at follow-up (three months).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 22/05/2022, London - Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 1048098; harrow.rec@hra.nhs.uk), ref: 22/LO/0273

## **Study design**

Parallel-group superiority interventional single-blind randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Non-affective psychosis with low positive self-belief

## **Interventions**

Participants will be NHS patients diagnosed with non-affective psychosis, with low positive self-beliefs, and aged 16-30 years old. It is a parallel group randomised controlled trial in which participants will be randomised to receive the intervention in addition to their usual care or will continue with their usual care. Participants will be allocated using a 1:1 allocation ratio. Randomisation will use a permuted blocks algorithm, with randomly varying block sizes.

The treatment being tested is Phoenix VR self-confidence therapy, which is a virtual-reality application recommended for adults (16+) attending psychosis services who have low levels of positive self-beliefs. The primary treatment goal is to help young people who have been given a diagnosis of schizophrenia (or related condition) to increase their psychological well-being by building up positive self-beliefs.

Phoenix is supported by a staff member in up to 6 meetings. In the first meeting, the staff member introduces Phoenix and helps the person try it out. The staff member also helps the person set real-world goals and between-session tasks to improve confidence, and reviews progress. Patients can keep the headset for six weeks in order to use Phoenix on their own. Phoenix has three main therapeutic areas within VR for the user: creating a sense of achievement and mastery to develop the belief 'I can make a difference'; succeeding in challenging situations to develop the belief 'I can do this'; and engaging in pleasurable activities to develop the belief 'I can enjoy things'. The achievement and mastery scenario is set in a community garden, with ten tasks relating to the care of plants, animals, and a farmhouse. The challenging situation is a TV studio, with the user having to speak to the camera in front of an audience. There are ten levels of difficulty. The pleasurable experiences are set near a lake by a forest and tasks include relaxation exercises and games. A virtual coach (called Farah) guides the participant in the best way to think, feel, and respond. Patients choose which VR scenarios they wish to complete, and can repeat activities as often as they would like. The sessions can take place at home, in the clinic, or in a psychiatric ward.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Phoenix VR self-confidence therapy app

## **Primary outcome(s)**

Positive self-beliefs measured by the Oxford Positive Self Scale [OxPos]. Timepoint(s): baseline, 6 weeks, and 12 weeks. The primary endpoint is 6 weeks.

## **Key secondary outcome(s)**

1. Psychological well-being measured by the Warwick-Edinburgh Wellbeing Scale. Timepoint(s): baseline, 6 weeks, and 12 weeks.
2. Social comparison and negative and positive self-beliefs measured by the Social Comparison Scale, the Brief Core Schema Scale (Negative and Positive Self) and the Everyday Confidence Scale. Timepoint(s): baseline, 6 weeks, and 12 weeks.
3. Depression, hopelessness, and anhedonia measured by the Patient Health Questionnaire-9 (PHQ-9), Beck Hopelessness Scale, Temporal Experience of Pleasure Scale (anticipatory pleasure scale). Timepoint(s): baseline, 6 weeks, and 12 weeks.
4. Anxiety measured by the Generalized Anxiety Disorder Assessment-7 (GAD-7). Timepoint(s): baseline, 6 weeks, and 12 weeks.
5. Paranoia measured by the Revised Green et al Paranoid Thoughts Scale (Revised GPTS). Timepoint(s): baseline, 6 weeks, and 12 weeks.
6. Perceptions of recovery measured by the Questionnaire about the Process of Recovery (QPR). Timepoint(s): baseline, 6 weeks, and 12 weeks.
7. Meaningful activity measured by the Time Budget. Timepoint(s): baseline, 6 weeks, and 12 weeks.
8. Quality of life measured by the EQ-5D and Recovery Quality of Life questionnaire (ReQoL). Timepoint(s): baseline, 6 weeks, and 12 weeks.
9. Satisfaction ratings for Phoenix VR measured by the Modified Client Satisfaction Questionnaire (intervention group only). Timepoint(s): 6 weeks.
10. Side effects measured by the Oxford - VR Side Effects Scale (intervention group only). Timepoint(s): 6 weeks.

## **Completion date**

30/06/2026

## **Eligibility**

### **Key inclusion criteria**

1. Participant is willing and able to give informed consent for participation in the trial.
2. Aged between 16 years and 30 years old.
3. Attending NHS mental health services for treatment of psychosis.
4. Primary clinical diagnosis of non-affective psychosis (schizophrenia, schizoaffective disorder, delusional disorder, or psychosis NOS).
5. Low levels of positive self-beliefs indicated by a score of 50 or lower on the Oxford Positive Self Scale (OxPos).
6. Stable medication for at least one month and no planned significant changes at the outset of participation.

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

16 years

**Upper age limit**

30 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. A primary diagnosis of another mental health condition (e.g. substance use disorder) that would be the first clinical priority to treat.
2. Current engagement in any other intensive individual psychological therapy.
3. In forensic settings or Psychiatric Intensive Care Unit (PICU).
4. Command of spoken English inadequate for engaging in the VR therapy.
5. Photosensitive epilepsy or significant visual, auditory, or balance impairment that would make use of VR inappropriate.
6. Significant learning difficulties that would prevent the completion of assessments.
7. A participant may also not enter the trial if there is another factor (for example, current active suicidal plans), 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**

12/06/2023

**Date of final enrolment**

31/03/2026

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Oxford Health NHS Foundation Trust**

Warneford Hospital

Warneford Lane

Headington  
Oxford  
England  
OX3 7JX

**Study participating centre**  
**Berkshire Healthcare NHS Foundation Trust**  
Fitzwilliam House  
Skimped Hill Lane  
Bracknell  
England  
RG12 1BQ

**Study participating centre**  
**Northamptonshire Healthcare NHS Foundation Trust**  
St Marys Hospital  
77 London Road  
Kettering  
England  
NN15 7PW

**Study participating centre**  
**Central and North West London NHS Foundation Trust (specifically teams in Milton Keynes)**  
Trust Headquarters  
350 Euston Road  
Regents PLACE  
London  
England  
NW1 3AX

## **Sponsor information**

**Organisation**  
University of Oxford

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

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

International Foundation

**Funder Name**

NIHR Oxford Health Biomedical Research Centre

## Results and Publications

**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 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?
<a href="#">Protocol article</a>		07/12/2023	27/12/2023	Yes	No