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The Phoenix virtual reality self-confidence study

Submission date	Recruitment status	[X] Prospectively registered
12/05/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/06/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/10/2024	Mental and Behavioural Disorders	[X] 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 Pheonix 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 August 2024. The clinical trial will start in June 2023 and finish 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

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312539

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
16125, IRAS 312539

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

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Other therapist office, Other

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
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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Phoenix VR self-confidence therapy app

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2021

Completion date
31/08/2024

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

Age group
Mixed

Lower age limit
16 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
80

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
30/04/2024

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
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital
77 London Road
Kettering
United Kingdom
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
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NW1 3AX

Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Website
http://www.ox.ac.uk/

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

Publication and dissemination plan
The study protocol will be submitted to a journal within three months of trial registration. The main outcome paper will be submitted to a peer-reviewed journal.

Intention to publish date
28/02/2025

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?
Protocol article		07/12/2023	27/12/2023	Yes	No