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Developing immersive virtual exposures for obsessive-compulsive disorder

Submission date
23/12/2025

Recruitment status
No longer recruiting

Registration date
29/12/2025

Overall study status
Completed

Last Edited
29/12/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Obsessive–compulsive disorder (OCD) is a mental health condition that can cause distressing thoughts and repetitive behaviours. One of the most effective treatments for OCD is exposure and response prevention (ERP) therapy, which helps people gradually face their fears and tolerate discomfort. However, some people find it difficult to engage fully with exposure exercises and adhere to the therapeutic process, which hinders its efficacy. New technologies, such as virtual reality (VR) and artificial intelligence (AI), may help make exposure therapy more engaging and personalised.
This study aims to assess the feasibility, acceptability, and safety of a new artificial intelligence (AI)–generated exposure system for people with OCD. This study will explore emotional engagement with the exposure content when delivered via immersive virtual reality (VR) and via a screen-based format, as well as in comparison to neutral content.

Who can take part?
Adults aged 18–65 with a diagnosis of moderate to severe OCD who are receiving outpatient psychiatric care at the Champalimaud Clinical Centre.

What does the study involve?
Participants will be randomly allocated to one of three groups:
1. OCD-related exposure delivered in virtual reality
2. Neutral (non-threatening) virtual reality environments
3. OCD-related exposure delivered on a large screen

All participants will receive two standard ERP therapy sessions with a trained therapist. In addition, they will complete five short daily exposure sessions using their allocated technology, between the ERP sessions The exposure content is personalised for each participant and carefully reviewed by clinicians to ensure safety. Participants will be monitored throughout. Researchers will measure distress, physiological responses (such as heart rate and skin conductance), cybersickness, usability, and safety.

What are the possible benefits and risks?
Participants may benefit from taking part in structured exposure exercises and from

contributing to research that could improve future OCD treatments. Temporary anxiety during exposure may occur as part of therapy. Clinicians will be present to ensure safety and provide support if needed.

Where is the study run from?
King's College London (UK) in collaboration with Champalimaud Foundation (Portugal).

Who is funding the study?
UK Department for Science, Innovation and Technology.

Who are the main contacts for this study?
1. Dr Mariana Pinto da Costa at King’s College London (Chief Investigator in the UK), mariana.pintodacosta@kcl.ac.uk
2. Dr Albino Oliveira Maia at Champalimaud Foundation (Principal Investigator in Portugal), albino.maia@research.fchampalimaud.org

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Contract
5368451

Study information

Scientific Title
Developing immersive virtual exposures for obsessive-compulsive disorder – Protocol for a Randomised, Controlled, Proof-of-Concept Feasibility Trial

Acronym
DIVE-OCD

Study objectives

To investigate if generative AI-driven virtual reality technology, delivered through VR headsets is feasible, acceptable and safe

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/10/2025, Champalimaud Foundation's Ethics Committee (Avenida de Brasília 66, Lisbon, 1200, Portugal; +351 210480200; ethics@research.fchampalimaud.org), ref: 07102025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive-Compulsive Disorder

Interventions
3 Arms:
AI-generated OCD immersive VR exposure
AI-generated OCD-related exposure via widescreen display
Neutral immersive VR exposure (control)

Arm 1: AI-generated OCD-related immersive VR exposure
Participants receive OCD-related exposure content generated using a generative AI system and delivered via an immersive virtual reality headset. Exposure scenarios are personalised based on each participant’s individual OCD symptom profile and exposure hierarchy, and reviewed by a clinician prior to use. Participants complete five short daily VR exposure sessions under clinical supervision, in addition to standard ERP sessions.

Arm 2: AI-generated OCD-related exposure delivered on a large screen
Participants receive OCD-related exposure content generated using a generative AI system,

reviewed by a clinician prior to use, and delivered via a large widescreen (non-immersive) display. Participants complete five short daily exposure sessions under clinical supervision, alongside standard ERP sessions.

Arm 3: Neutral (non-threatening) immersive VR exposure
Participants receive immersive VR exposure to neutral, non-threatening environments, without OCD-related content. Participants complete five short daily VR sessions, reviewed by a clinician prior to use, alongside standard ERP sessions.

In the three arms, the total intervention duration is approximately 14 days. This includes the eligibility and assessment visit (Visit 1). This is followed by randomisation to one of the three study arms. One ERP session (Visit 2A, baseline) takes place 2 to 7 days after the assessment visit, followed by five technology-assisted exposure sessions (Visit 2B, Visit 3, Visit 4, Visit 5 and Visit 6), and one final ERP session (Visit 7A). This intervention sequence is identical across all study arms.

Randomisation:
Participants are randomly allocated (1:1:1) to one of three study arms. A stratified permuted block randomisation method with variable block sizes will be used to ensure unpredictability and allocation balance throughout the recruitment period. Allocation is concealed from outcome assessors.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility, acceptability and safety of the intervention measured using recruitment rate (number of participants enrolled within the recruitment window), retention rate (number of enrolled participants completing the final assessment), adherence (proportion of planned exposure sessions completed; completion defined as 30-minute duration with post-session ratings provided), participant-reported acceptability and usability (assessed through end-of-study qualitative interviews), and adverse events monitoring at throughout the intervention and at the end of the intervention (approximately 7 days from baseline)

Key secondary outcome(s)
1. Physiological reactivity measured using electrodermal activity (microsiemens) and heart rate (beats per minute) standardized within participants relative to within-session baseline at at Visit 2A (baseline) and during each asynchronous exposure session: Visit 2B (same day as baseline Visit 2A), Visit 3 (1 day after baseline), Visit 4 (2 days after baseline), Visit 5 (3 days after baseline), Visit 6 (4 days after baseline), and Visit 7A (approximately 7 days after baseline)

2. Cybersickness measured using Simulator Sickness Questionnaire (SSQ) at after each virtual reality exposure session at Visit 2B (same day as baseline), Visit 3 (1 day after baseline), Visit 4 (2 days after baseline), Visit 5 (3 days after baseline) and Visit 6 (4 days after baseline)

3. General distress and state anxiety measured using Visual analogue scale (0-10) and State-Trait Anxiety Inventory State version (STAI-Y1) at after each exposure session at Visits 2B (same day as baseline), Visit 3 (1 day after baseline), Visit 4 (2 days after baseline), Visit 5 (3 days after baseline) and Visit 6 (4 days after baseline)

4. Subjective exposure progression measured using hierarchy position score (percentage progression through the individualised Subjective Units of Distress Scale [SUDS] hierarchy) at from Visit 2A (baseline) to Visit 7A (approximately 7 days after baseline)

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 to 65 years
2. Primary diagnosis of OCD confirmed by Mini International Neuropsychiatric Interview (MINI 5.0.0)
3. Y-BOCS-II score ≥ 14 (moderate to extremely severe symptoms)
4. At least one OCD subtype amenable to visual exposure (contamination/washing, checking, or symmetry/ordering)
5. Ability to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Predominant OCD symptoms not suitable for visual exposure
2. Current or past psychotic episode, schizophrenia, or autism spectrum disorder
3. Current substance use disorder
4. Self-reported history of severe cardiovascular disease where acute physiological arousal poses a safety risk, defined as the presence of an implanted cardiac device (pacemaker or ICD), a diagnosis of heart failure or aortic aneurysm, or the occurrence of a major cardiac event (myocardial infarction, stroke, or cardiac surgery) within the past 12 months
5. Visual or auditory impairment, motion sickness susceptibility, or epilepsy

Date of first enrolment

05/01/2026

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
United Kingdom

England

Portugal

Study participating centre
King's College London
16 De Crespigny Park
London
England
SE5 8AB

Study participating centre
Champalimaud Clinical Centre
Avenida de Brasília 66
Lisbon
Portugal
1200

Sponsor information

Organisation
Champalimaud Foundation

ROR
https://ror.org/03g001n57

Funder(s)

Funder type
Not defined

Funder Name
Department for Science, Innovation and Technology

Alternative Name(s)
Department for Science, Innovation & Technology, Department for Business, Energy and Industrial Strategy, Department for Digital, Culture, Media and Sport, DSIT, BEIS

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