ISRCTN63031617 https://doi.org/10.1186/ISRCTN63031617

Adding virtual reality to talking therapy for post-traumatic stress disorder: a feasibility study

Submission date
18/08/2026

Recruitment status
Recruiting

Registration date
24/08/2026

Overall study status
Ongoing

Last Edited
25/09/2026

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
Post-traumatic stress disorder (PTSD) can be very distressing. A talking therapy called eye movement desensitisation and reprocessing (EMDR) is a recommended treatment, but access is often limited by how many in-person sessions clinicians can offer. This study tests whether giving patients a virtual reality (VR) headset to use at home, alongside their usual EMDR sessions, is a safe, practical and acceptable way to support their treatment. As this is a feasibility study, the main aim is to find out whether this "blended care" approach works well in practice, before a larger trial is carried out.

Who can participate?
Patients aged 18 years or over with a primary diagnosis of PTSD

What does the study involve?
Participants are randomly allocated (like flipping a coin) to one of two groups. Both groups receive six weekly sessions of standard, in-person EMDR therapy from a qualified clinician. Participants in the intervention group are additionally given a VR headset to take home for a 3-week period, during which they use it for 40-50 minutes roughly every other day to complete therapeutic exercises, with their clinician monitoring progress and adjusting the schedule as needed. All participants complete questionnaires about their PTSD, mood and anxiety symptoms at the start, middle and end of the 6-week treatment period.

What are the possible benefits and risks of participating?
All participants receive standard EMDR therapy, a treatment recommended by NICE guidance for PTSD. Those in the VR group may benefit from more flexible and frequent treatment, which could help them engage more with their recovery, though this has not yet been proven. Possible risks include increased emotional distress if home-based trauma processing is difficult to tolerate, mild physical discomfort (such as nausea or eye strain) from using a headset, and a small risk of minor injury during unsupervised home use. These risks are reduced through in-clinic training before home use, a maximum session length, built-in prompts to support grounding exercises, weekly clinical monitoring, and a clear crisis plan given to every participant.

Where is the study run from?
The study is coordinated by Reinhart (UK) and is being run from three sites in England: Avon and Wiltshire Mental Health Partnership NHS Trust (Bath), Nightingale Hospital (London) and The Soke (London).

When is the study starting and how long is it expected to run for?
August 2026 to April 2027

Who is funding the study?
Innovate UK

Who is the main contact?
Dr Francis Madden, francis@reinhart.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
365747

Central Portfolio Management System (CPMS)
72883

Study information

Scientific Title
A multi-centre, randomised controlled feasibility trial comparing virtual reality-enhanced blended care versus standard eye movement desensitization and reprocessing therapy for adults with post-traumatic stress disorder

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/06/2026, South East Scotland REC 02 (Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)131 465 5679; loth.sesres@nhs.scot), ref: 26/SS/0056

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Post-traumatic stress disorder (PTSD)

Interventions
Participants are randomised 1:1 to the intervention or control group using permuted block randomisation with varying block sizes. The randomisation sequence is managed through a secure, central online randomisation service to ensure allocation concealment.

Control Group:
Participants receive 6 weekly sessions of standard in-person Eye Movement Desensitization and Reprocessing (EMDR) therapy delivered by a qualified clinician

Intervention Group:
Participants receive standard weekly in-person EMDR therapy combined with a fixed 3-week home-use block. During this block, participants self-administer a 40–50 minute adjunctive trauma processing session every other day (targeting 3–4 sessions per week) utilising the Psylaris EMDR-VR medical device.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VR EMDR

Primary outcome(s)
1. Feasibility adherence rate measured using the proportion of prescribed home-use sessions successfully completed, extracted objectively via the VR software's internal logs at continuously monitored over the 3-week active home-use block (assessed at week 6 end of treatment)

Key secondary outcome(s)
1. Clinical efficacy (PTSD severity) measured using the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition PTSD Checklist (DSM-5 PCL-5) score at baseline (week 1), midpoint (week 3/VR start), and end of treatment (week 6)

2. Clinical efficacy (comorbidities) measured using the Patient Health Questionnaire-9 (PHQ-9) for depression and Generalized Anxiety Disorder-7 (GAD-7) for anxiety at baseline (week 1), midpoint (week 3/VR start), and end of treatment (week 6)

3. Safety profile measured using the incidence and frequency of adverse device effects (ADEs) at tracked continuously throughout the 6-week trial duration

4. Usability/acceptability measured using the System Usability Scale (SUS) and User Experience Questionnaire - Short Version (UEQ-S) at week 6 post-treatment (intervention group only)

Completion date
11/04/2027

Eligibility

Key inclusion criteria
1. Capable of giving informed consent
2. Male or female adults aged 18 years or over
3. Primary diagnosis of post-traumatic stress disorder (PTSD) (relating to single-event or multiple /complex trauma) confirmed by a clinician
4. Proficient in English (sufficient to complete assessments and engage with the therapy /software)
5. Willing to be randomised to either treatment group (Standard Care or Blended VR Care)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

999 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Currently receiving another formal psychotherapy for PTSD or anxiety
2. Current severely dependent substance use disorder
3. Active suicidal ideation or intent, or a recent suicide attempt
4. Presence of severe mental health conditions that would interfere with participation or safety, specifically active psychosis, severe depression requiring inpatient care, or Dissociative Identity Disorder (DID)
5. Medical conditions that contraindicate EMDR therapy, such as uncontrolled seizure disorders
6. Medical conditions that contraindicate Virtual Reality use, such as severe history of motion sickness or specific visual impairments that prevent the use of the headset
7. Known inability to use or tolerate VR or AR equipment
8. Currently involved in a conflicting clinical trial for an investigational drug or device

Date of first enrolment
24/08/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Nightingale Hospital
11-19 Lisson Grove

London
England
NW1 6SH

Study participating centre
The Soke
241 Fulham Road
London
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SW3 6HY

Sponsor information

Organisation
Reinhart Group Ltd

Funder(s)

Funder type

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised participant-level data may be made available to external researchers upon reasonable request and approval by the Trial Management Group, following publication of the

primary results. The final dataset will be accessible to the Chief Investigator, the trial statistician, and the Trial Management Group.

IPD sharing plan summary

Available on request