# VR in major trauma rehab: a qualitative study

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
05/05/2025		[X] Protocol		
Registration date	Overall study status Ongoing	Statistical analysis plan		
21/05/2025		☐ Results		
Last Edited	Condition category Injury, Occupational Diseases, Poisoning	Individual participant data		
21/05/2025		[X] Record updated in last year		

### Plain English summary of protocol

Background and study aims

Following serious injuries (major trauma), rehabilitation is very important. It helps people regain their strength, movement, and independence. VR is the name for computer technology that makes a person feel like they are somewhere else. More recently, people are using VR through a headset. The headset is worn over a person's eyes and shows a close-up screen. VR headsets have applications or 'Apps' (like on your mobile phone) which offer games, exercises, guided relaxation, or relaxing scenery. VR could help people recover from injuries. It might make rehab more fun and engaging. VR is starting to be used more in healthcare as a way of helping patients recover. But we have lots to learn about the best ways to use it to help patients. Following major trauma, rehabilitation starts early in the acute hospital setting and can be a gruelling process due to pain, fear of movement, post-traumatic stress, and anxiety. There are several physical and mental barriers that patients feel towards rehabilitation in the hospital. After serious injury, patients who are worried about the threat of pain have been shown to have worse outcomes. Exposure to movement is an effective way to lessen patients' fear of moving due to pain. In other health conditions, the use of VR headsets has been shown to decrease anxiety, pain and the time spent thinking about pain. Usually, this is using the relaxing types of VR. Given the benefits of exposure to movement and the importance of not becoming weaker, we want to know if a more physically active VR treatment could be beneficial for patients' rehabilitation. To the best of our knowledge, there is no research looking at patients' experience of using VR headsets for rehabilitation following serious injury. The study will explore whether patients find VR headsets helpful and acceptable during their rehabilitation in the hospital. This study aims to find out if using virtual reality (VR) headsets can make rehab better, and what people think of using them in the hospital.

### Who can participate?

People aged over 18 years who have experienced major trauma injuries and use VR headsets during their rehab in the hospital

### What does the study involve?

Patients who agree to take part will have a 30-minute interview with a researcher, which can be in person or done by video call. They will be asked to sign a consent form and fill in a short form about themselves and their injuries. Patients will be asked about their experiences of using VR headsets during their rehab in the hospital to explore what they liked or didn't like about them, and if they found them helpful.

What are the possible benefits and risks of participating? Benefits: The study could help improve rehabilitation for future trauma patients.

Risks: Reflecting on the recovery from serious injuries may be emotionally challenging. They can stop taking part at any time, without giving a reason.

Where is the study run from? City, St George's University of London, UK

When is the study starting and how long is it expected to run for? August 2024 to September 2025. The study has approval to start in December 2025. Interviews will be conducted within 6 months and the study will be written up by September 2025.

Who is funding the study?

There is no additional funding for the study, it is being conducted as part of a Master's in Clinical Research.

Who is the main contact?
Bethany Kenny, Bethany.kenny@stgeorges.nhs.uk

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

#### Contact name

Mrs Bethany Kenny

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### Additional identifiers

### **EudraCT/CTIS** number

Nil known

#### IRAS number

346340

#### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

2024.0197

## Study information

#### Scientific Title

Patients experience and acceptability of using a virtual reality headset as an adjunct to rehabilitation following major trauma: an interview study

### **Study objectives**

To explore patients' experience and acceptability of using a physically active VR Headset intervention as an adjunct to their rehabilitation following major trauma via semi-structured interview.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 16/12/2024, West of Scotland Rec 3 (Admin Building, Level 2, 1055 Great Western Rd, Glasgow, G12 XH, United Kingdom; +44 (0)141 314 0212; ggc.WoSREC3@nhs.scot), ref: 24/WS/0158

#### Study design

Qualitative interview study

### Primary study design

Observational

### Secondary study design

Qualitative interview study

### Study setting(s)

Home, Hospital, Internet/virtual

#### Study type(s)

Treatment, Efficacy

#### Participant information sheet

See study outputs table

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

Inpatients with major trauma

#### **Interventions**

Currently St George's University hospital is running a quality improvement project looking at the use of a physically active VR headset interventions as an adjunction to their rehabilitation. Patients undergo a sessions of VR, up to 30min's. They can play physically active games such as boxing, goal keeping, fruit picking, swiping boxes with a sword in either a sitting lying or standing position. Patients who have experienced this intervention (atleast two times) are being invited to participate in a 30-min semi-structured interviews with the lead researcher. The

interview transcript is designed around the transtheoretical framework of acceptability (TFA), This framework posits seven constructs that reflect the underlying key dimensions of acceptability of new healthcare interventions (Affective attitude, Burden, intervention coherence, ethicality, opportunity costs, perceived effectiveness and self-efficacy).

### Intervention Type

Device

### Pharmaceutical study type(s)

Not Applicable

#### Phase

Not Applicable

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

Sync VR medical, PICO Headset

### Primary outcome measure

The outcomes will be drawn from thematic analysis of the semi-structured interviews. Intereview we be examined to assess the patients perspective of acceptability of the intervention.

To analyse data relating to acceptability a 2-stage process with be completed. In stage 1, text from the interview transcripts will be deductively coded into the seven TFA constructs to provide the core corpus of data for analysis. In stage 2, text within each construct will be inductively analysed to construct themes that reflect the content and meaning of the data.

### Secondary outcome measures

There are no secondary outcome measures

### Overall study start date

30/07/2024

### Completion date

30/09/2025

## **Eligibility**

### Key inclusion criteria

- 1. Participants aged 18 and over
- 2. Who sustained Major Trauma injuries as per the TARN inclusion criteria, who used a physically active Virtual reality headset as an adjunct to their rehabilitation on the major trauma ward

### Participant type(s)

**Patient** 

### Age group

Adult

### Lower age limit

18 Years

#### Sex

Both

### Target number of participants

15

#### Key exclusion criteria

- 1. Unable to speak fluent English
- 2. Those who lack capacity to engage in the formal consent process or where the treating clinicians (e.g. doctor or occupational therapist) feels that there is cognitive impairment present that would impact the patient from engaging in an in-depth semi-structured interview

  3. A prisoner or vulnerable adult who will have difficulties organising and attending a face-to-
- 3. A prisoner or vulnerable adult who will have difficulties organising and attending a face-to-face or over the phone interview safely and conveniently

#### Date of first enrolment

01/02/2025

#### Date of final enrolment

30/06/2025

### Locations

### Countries of recruitment

England

**United Kingdom** 

### Study participating centre St George's University Hospital NHS Foundation trust

Blackshaw Rd London United Kingdom SW17 0QT

## Sponsor information

#### Organisation

City St George's, University of London

#### Sponsor details

Cranmer Terrace London England United Kingdom SW17 0RE +44 (0)2087254077 researchgovernance@sgul.ac.uk

### Sponsor type

University/education

#### Website

https://www.citystgeorges.ac.uk/

#### **ROR**

https://ror.org/047ybhc09

## Funder(s)

### Funder type

Other

#### **Funder Name**

Investigator initiated and funded

### **Results and Publications**

### Publication and dissemination plan

The study will be submitted for academic marking in September 2025 and planned to be submitted for publication in a peer-reviewed journal following this.

Outcomes will be disseminated at national or international conferences.

### Intention to publish date

08/10/2025

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		14/01/2025	21/05/2025	No	Yes
Participant information sheet	Consent form	14/01/2025	21/05/2025	No	Yes
<u>Protocol file</u>	version 2.1	06/02/2025	21/05/2025	No	No