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Testing to see how virtual reality mindfulness and wellbeing session before and after cardiac surgery will help to reduce anxiety and stress

Submission date 03/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 05/01/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/09/2024	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-drug methods like hypnosis and Virtual Reality (VR) are used alongside other treatments to help patients with anxiety and different types of pain. But when it comes to using VR to help people who are having heart surgery, there haven't been many studies. One reason for this might be that using VR for this purpose is relatively new, VR technology is changing quickly, and it can be expensive to get started with VR.

This pilot study will assess immersive head-mounted VR simulations in adult patients undergoing first-time elective cardiac surgery to understand the impact on patient anxiety and stress. The primary objective is to assess anxiety and stress levels between two groups.

Who can participate?
Patients aged 18 years or older, undergoing cardiac surgery at Wythenshawe Hospital.

What does the study involve?
Patients will be randomly assigned to two groups: one receiving standard care (control group) and the other receiving VR intervention. The control group will go through the regular admission process, including informational resources and music sessions using a wireless headset. The VR group will receive the same, but with additional VR sessions before surgery and on the third day after surgery. We will exclude patients requiring ventilation on the third day and replace them with new participants in both groups. Both groups will complete questionnaires before and after surgery to assess anxiety and stress levels. Physiological assessments, VR experience, and absorption will be recorded for the VR group. Additionally, we will explore the relationship between salivary cortisol levels (a potential stress biomarker) and self-reported anxiety levels using questionnaires. Four sets of samples will be collected before and after the placebo/VR interventions to examine the correlation.

What are the possible benefits and risks of participating?
Benefits: The potential benefit if you are allocated to try the Virtual Reality immersive intervention is reduced stress, anxiety and improved wellbeing and mindfulness after using the

device.
Risks: Some people may experience nausea, dizziness, disorientation, balance problems, headache, eye strain or fatigue when using VR headsets, although this is rare. If you experience any of these symptoms, or feel uncomfortable in any way, you are free to remove the headset at any time and you do not need to carry on with the study.
In addition, there is a risk of cross-contamination of infection from one patient to another patient when using VR headsets and headphones. To avoid any possible cross-contamination, we will be cleaning the headphones and headsets with alcoholic disinfectant frequently.

Where is the study run from?
University of Salford (UK)

When is the study starting and how long is it expected to run for?
January 2024 to June 2024

Who is funding the study?
University of Salford (UK)

Who is the main contact?
Prof Bhuvaneswari Krishnamoorthy, b.bibleraaj@salford.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335136

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 335136

Study information

Scientific Title
A Randomised pilot Study to evaluate the use of Virtual Reality Mindfulness and Wellbeing session during pre- and post-surgical admission to reduce anxiety and stress undergoing first time elective cardiac surgery – RSVR study

Acronym
RSVR

Study objectives
The use of Immersive head mounted Virtual Reality headset intervention can reduce pre-and postoperative anxiety and stress in adult patients undergoing elective cardiac surgery

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/01/2024, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 207 104 8290; gmeast.rec@hra.nhs.uk), ref: 23/NW/0345

Study design
Single-centre two-arm randomized controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Laboratory, Medical and other records

Study type(s)
Quality of life, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Pre-and postoperative anxiety and stress in adult patients undergoing elective cardiac surgery

Interventions

Cardiac surgery patients (n = 30) undergoing first time elective/urgent-in-patient cardiac surgery at Wythenshawe Hospital site will be randomly assigned equally to two arms (control with placebo or VR) using a computer-generated randomisation list. The control group will receive standard care admission process which includes a surgical information booklet, online Microsoft Teams experiential talk about the surgery pathway by a heart charity and two sessions of 15 minutes music session with WorWoder Wireless blue tooth headset as a placebo pre- and post-surgery as same timings as intervention group. The VR intervention group will receive the same as the control group with the addition of two VR sessions: session one 15 minutes VR session will be one hour before surgery and sessions two on day 3 evening (around 6pm) postoperatively. Patients who are ventilated on day 3 will be removed from the study and additional patients will be recruited on both groups. Questionnaires will be handed to the patients pre- and post-surgery in both groups to rate their levels of anxiety and stress level (STAI), physiological assessments, VR experience and VR-absorption (VAS) in intervention group will be recorded.
In addition, we will explore if there is association between salivary cortisol levels as a potential biomarker for stress and self-completed questionnaires anxiety level (STAI). We will obtain four samples of before and after placebo/VR intervention pre- and post-surgery to see the co-relation.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VR experience from Rescape Innovations (https://www.rescape.health/)

Primary outcome measure
Patients' anxiety and stress levels measured using STAI before and after each session on pre- and post-surgery

Secondary outcome measures
1. Cortisol swabs before & after each session on pre- and post-surgery
2. Physiological parameters pre- and post-surgery in each session:
2.1. Heart rate measured using Holter monitor which is standard in all cardiac wards at the NHS hospital
2.2. Blood pressure measured using Holter monitor which is standard in all cardiac wards at the NHS hospital
2.3. Respiratory rate measured using direct observation by the researcher

Overall study start date
02/01/2024

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Adults undergoing first-time elective cardiac surgery (coronary artery bypass surgery and aortic/mitral valve surgeries)
2. Age more than 18 years
3. Give informed consent for their participation to this study
4. Urgent inpatients who are well enough to read and understand the study and patient information leaflet

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
30

Total final enrolment
36

Key exclusion criteria
1. Psychiatric antecedents, claustrophobia or acrophobia, diagnosis or self-reported anxiety disorder, hearing or visual impairment, Infectious cases (example: conjunctivitis), redo surgery, critical preoperative state, impaired cognitive function, current diagnosis of epilepsy, dementia, or other neurologic disease, receipt of anxiolytic drugs or sedatives within the preceding 24 hours, or injury to the face, or non-infectious, infectious skin conditions that would prevent comfortable use of the VR hardware.
2. Patients who are having complex cardiac surgeries.
3. Patients who are admitted for an emergency cardiac surgery.
4. Patients who do not want to listen to music on their bedside Bluetooth enabled headphones.
5. Patients who do not want to wear VR headsets.

Date of first enrolment
05/02/2024

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Wythenshawe Hospital
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Sponsor information

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
University of Salford Manchester

Alternative Name(s)
University of Salford, University of Salford, Manchester, USM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study data will be presented at national and international conferences and published in a peer reviewed journal.

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
All data will be anonymised. Patients who have consented to get a copy of the results will be posted to their home address.
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request and will be included in the subsequent results publication.
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IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0.2	12/12/2023	05/01/2024	No	Yes
Protocol file	version 0.1	03/10/2023	05/01/2024	No	No