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Development and testing of a virtual reality tool to support recovery in people after they have left intensive care

Submission date 22/06/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 18/08/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 15/08/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
People admitted to intensive care (ICU) often experience ongoing health problems once they leave and have returned home. This is described as Post Intensive Care Syndrome (PICS) and can include problems with memory and thinking, physical impairments and reduced psychological wellbeing. This can result in a reduced quality of life, which also affects family members and friends. Although improvements have been made in caring for people within ICU, there is no standard approach to care after leaving ICU to support patients' recovery. A lack of staff and resources have also been a barrier to standard post -ICU care. With the recent increase in admissions to ICU, there is an urgent need to find ways of supporting the recovery of people with PICS that is readily available to patients. A recent review of how to combat PICS suggested that home-based and virtual care plans would be one way of making sure that as many people as possible could take advantage of rehabilitation support.
Immersive virtual reality (VR) can be accessed simply at home with an easy -to-use headset. VR has already been shown to be useful in helping relaxation and in combatting pain and anxiety. We think that VR might help support people recovering from PICS at home and this study is aimed at developing a VR program (intervention) that can be used at home.

Who can participate?
Phase 1 - We are looking for people who have experienced, or people who are family members of those who have experienced a stay in intensive care within the last five years.
Phase 3 - We are looking for people with a recent admission (within the last 4 weeks) to ICU and who required organ support during their ICU stay for at least 48hrs or more.

What does the study involve?
We are proposing a three stage program of research. First, we need to understand what the recovery journey looks like. We will conduct a series of focus groups with ICU survivors, their family members and healthcare professionals involved in the care and rehabilitation of ICU patients. In these sessions, we will explore what the patient recovery journey looks like and what the critical parts of recovery are. We will also work with these groups to determine, in terms of recovery, what is important to measure (known as outcomes) to find out whether or not a

homebased care intervention works.
The second stage will use data from the focus groups which will then be used to alter an existing VR set-up (DR.VR) to specifically support the recovery of ICU patients, working with previous ICU patients and their family members to inform the design. We will also ask this group what features need to be included when testing the intervention at home and use this input to design the next stage of the project.
In the third part of the study, we will test the adapted VR intervention in a small group of patients who have previously been admitted to ICU. The aim of this study will be to see if using a home-based VR intervention is possible and if people are happy and willing to use it. We will also explore how acceptable participants find the outcomes selected from the earlier focus groups. We will do this by interviewing participants about their experience. We will also interview the healthcare professionals involved in the care and rehabilitation of these participants to gather their views on the VR intervention. The interview data will be analysed qualitatively to provide an in-depth understanding of the intervention and outcomes. This data can then be used to inform the design of larger studies in the future to test how effective the VR intervention is at supporting the recovery of ICU patients.
At the end of the study, we will share the results with all of the study participants and more widely through appropriate web pages, social media and organisations concerned with the care of ICU patients.

What are the possible benefits and risks of participating?
We do not know, at this time, if taking part in this research will have any direct benefit to participants or to their health. In the Phase 1 focus groups, we will talk to people about their experiences of being in intensive care, or having a loved one in intensive care. Recollection of these memories may be distressing, but the team includes a clinical psychologist who specialises in supporting people after ICU, who will be able to sign post participants to the appropriate support. However, some people may find that talking about these experiences makes them feel better. For the phase 3 study where we are testing the virtual reality tool designed in Phase 1&2 in people's homes. The use of the virtual reality equipment is known to be safe and we don't think there are any risks to taking part in this testing, but if participants do experience any problems, they can contact the study team immediately.

Where is the study run from?
Cwm Taf University Health Board (UK)

When is the study starting and how long is it expected to run for?
October 2022 to August 2025

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Ceri Lynch, Ceri.Lynch5@wales.nhs.uk
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Dr Kim Smallman, SmallmanK@cardiff.ac.uk

Study website
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/vr-ready

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
323989

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56995, IRAS 323989

Study information

Scientific Title
Virtual Reality to Aid Recovery Post-ICU. How can immersive virtual reality be used to facilitate recovery and rehabilitation of patients following a stay in intensive care?

Acronym
VR-READY

Study objectives
How can immersive virtual reality be used to facilitate recovery and rehabilitation of patients following a stay in intensive care?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/06/2023, North East- York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8079; york.rec@hra.nhs.uk), ref: 23/NE/0113

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Perioperative medicine and pain management

Interventions
Current interventions as of 11/10/2024:

The study is split into three phases.

Phase 1: In this phase of the study we will run a series of four focus groups each with a group of ICU survivors and/or their family members/ care partners and a separate group of health care professionals involved in facilitating the rehabilitation and recovery of ICU survivors. These sessions will focus on mapping the recovery pathway and identifying factors that might make it easier or more difficult to use a home-based VR mediated intervention. Additionally, these sessions will be used to explore and identify the most relevant outcomes to measure the utility of a home-based intervention to aid recovery in ICU survivors. The locations of focus groups will be chosen on a pragmatic basis for those involved, and will be in a non-hospital location (e.g. Rescape offices) for ICU survivors and their families to avoid any potential distress associated with returning to a hospital site.

Phase 2: Information gathered in phase 1 on the essential components for effective recovery and the experiences of ICU survivors will be used to modify existing DR.VR content, guided by ICU survivors to co-design a VR mediated intervention for home use to aid recovery following an ICU stay. Until the work is done, we do not know exactly what this will include but patient suggestions in our preparatory work included a 'virtual tour' of the intensive care unit, guided breathing and relaxation and physiotherapy exercises.

Phase 3: In this final part of the study, we will examine the feasibility and acceptability of the co-designed VR intervention in up to 20 people admitted to ICU in Cwm Taf Morgannwg University Health Board.
Informed by Phase 1, participants will be asked to use the VR READY intervention in hospital daily (a minimum of 5-10 minutes per day for a period of 2 weeks. If the participant is discharged during this time, they should continue with the intervention at home. If participants require assistance to use the equipment, this will be provided by a member of the research team. Participants will be asked to complete outcome measures at the beginning and end of this intervention period. No formal statistical analysis of outcomes will be performed- instead, the evaluation of outcomes will be qualitative in nature and centering on their feasibility and acceptability. Alongside this we will assess the feasibility and acceptability of the intervention and its delivery in a comprehensive process evaluation.

VR READY Content and Interface
When the user puts on the headset they will be able to view the ‘home screen’ menu which details the content contained on the device. This is divided into four sections;
1) Exploration – contains several different immersive environments with simple narration to introduce the user to that environment and invite them to explore the setting.
2) Mindfulness and Motivation – this section consists largely of original DR.VR content, with the addition of a bespoke motivational exercise.
3) Breathing – this section contains the original breathing exercises featuring in DR.VR, but which have been modified in terms of their speed, tailored to the expected capabilities of the participant population
4) Information – this contains a number of information videos featuring key staff roles encountered by patients when they are admitted to critical care.

When the user/ participant chooses a specific menu item they will be presented with the relevant sub-menu that details the specific content within that section.
Diversion/ Exploration
i) Underwater – a guided exploration of an underwater scene featuring a range of marine wildlife. “From the warm Caribbean Sea to the clear waters of the Pacific Ocean, you'll get to swim with some of the most majestic and endangered creatures on our planet. “
ii) Cities – a guided exploration of a busy city scape. “Travel to various cities from around the world. Enjoy your time there whilst listening to the history behind some of the world's most famous landmarks. “
iii) Travel – this provides the opportunity to experience a range of different worldwide locations. “The world is full of wonder and beauty. You'll get to travel to see some of the hidden wonders of the world, from exploding volcanoes to salmon fishing with black bears.”
iv) Wild Hikes - “A wild hike off the beaten track to amazing landscapes, remote beaches, extraordinary mountain ranges and lush green forests.”
v) Wildlife - “Sit and experience life up close and personal with some of the worlds most endangered animals from being as small as a bug to looking up at the tallest giraffe!”
vi) Space - Who hasn't dreamt of flying across the universe in your own spaceship?
Now you can! Visit the surface of mars and the rings of Saturn, with a few surprise stops along the way.”

Mindfulness and Motivation
i) Virtualisation for Motivation – this is a motivational script written by the VR READY consultant clinical psychologist in conjunction with the ICU survivors to provide reassurance and motivation to patients still on their recovery journey. The narration is set within a countryside setting, using aspects of the landscape as anchor points for the narrated content, including calming countryside soundscapes to aid relaxation.
ii) Sleep – “This guided relaxation experience will help you to relax after a long day and take a moment to recentre yourself. Choose from a variety of exercises from Muscle Relaxation to Belly Breathing from the commentary panel on the right and enjoy watching the sunset in a beautiful savanna.”
iii) Mindful Seeing – “This session will teach you how to mindfully look at the world. To stop and be in the moment, to take time to look at something beyond its label, and look at its colour, texture and shape.”
iv) Body Scan – “This session is a wonderful mindfulness session to reduce anxiety and stress. It will allow you to accept, with gentle curiosity, how your body is feeling.”
v) Calming Mind – “This session connects you with the water in a lake. Watching the ripples of water as you gain the space to calm your mind and bring perspective to your thoughts.”
vi) Mindful Listening – “This session gives us the space to really listen to the world around us. To stop and be within the moment. Mindful listening will allow you to take this practice into everyday life. really listening to the world around you.”

Breathing
i) Beach – This features a computer generated beach scene with accompanying soundscape where the user is guided through a breathing exercise “Relax and practice your breathing in a relaxing beach environment”
ii) Snow - This features a computer generated snowy scene with accompanying soundscape where the user is guided through a breathing exercise “Relax and practice your breathing in a relaxing snowy environment”
iii) Forest - This features a computer generated forest scene with accompanying soundscape where the user is guided through a breathing exercise “Relax and practice your breathing in a relaxing forest environment”

Information
i) Meet the psychologist – a consultant psychologist visits the patient in a hospital environment to explain their role and why the patient might interact with them.
ii) Meet the occupational therapist - an occupational therapist visits the patient in a hospital environment to explain their role and why the patient might interact with them.
iii) Meet the dietician - a dietician visits the patient in a hospital environment to explain their role and why the patient might interact with them.
iv) Meet the speech and language therapist - a speech and language therapist visits the patient in a hospital environment to explain their role and why the patient might interact with them.
v) Meet the physiotherapist- a physiotherapist visits the patient in a hospital environment to explain their role and why the patient might interact with them.

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Previous interventions:

The study is split into three phases.

Phase 1: In this phase of the study we will run a series of four focus groups each with a group of ICU survivors and/or their family members/ care partners and a separate group of health care professionals involved in facilitating the rehabilitation and recovery of ICU survivors. These sessions will focus on mapping the recovery pathway and identifying factors that might make it easier or more difficult to use a home-based VR mediated intervention. Additionally, these sessions will be used to explore and identify the most relevant outcomes to measure the utility of a home-based intervention to aid recovery in ICU survivors. The locations of focus groups will be chosen on a pragmatic basis for those involved, and will be in a non-hospital location (e.g. Rescape offices) for ICU survivors and their families to avoid any potential distress associated with returning to a hospital site.

Phase 2: Information gathered in phase 1 on the essential components for effective recovery and the experiences of ICU survivors will be used to modify existing DR.VR content, guided by ICU survivors to co-design a VR mediated intervention for home use to aid recovery following an ICU stay. Until the work is done, we do not know exactly what this will include but patient suggestions in our preparatory work included a 'virtual tour' of the intensive care unit, guided breathing and relaxation and physiotherapy exercises.

Phase 3: In this final part of the study, we will examine the feasibility and acceptability of the co-designed VR intervention in up to 20 people recently discharged from ICU in Cwm Taf Morgannwg University Health Board. The exact design of the study will be informed by the focus groups in Phase 1, but is expected that participants will be asked to use the DR.VR intervention at home for 8-12 weeks. Participants will be asked to complete outcome measures at the beginning and end of this intervention period. No formal statistical analysis of outcomes will be performed- instead, the evaluation of outcomes will be qualitative in nature and centering on their feasibility and acceptability. Alongside this we will assess the feasibility and acceptability of the intervention and its delivery at in a comprehensive process evaluation.

Intervention Type
Behavioural

Primary outcome measure

The primary outcome for the Phase 3 study is feasibility and acceptability as determined by; recruitment, retention, intervention adherence and data completion measured using patient records at the end of the study

Secondary outcome measures
Current secondary outcome measures as of 11/10/2024:

The secondary outcomes will include;
1. EQ5D
2. ICECAP-A
3. Brief resilience Scale
4. Richard Campbell Sleep Questionnaire
5. DASS-10

Previous secondary outcome measures:

The secondary outcomes to be included will be decided as part of Phase 1 activities and these will be updated on the conclusion of Phase 1 and phase 2. They are expected to include:
1. A quality of life measure, such as the EQ-5D or ICECAP-A
2. A measure of psychological well-being such as the hospital anxiety and depression scale (HADS)
3. General well-being scale
4. Sleep measure
5. A healthcare resource use measure
6. A measure of cognitive performance such as the Montreal Cognitive Assessment (MOCA)

Overall study start date
01/10/2022

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/10/2024:

1. People with a previous admission to critical care within the last five years
2. Family members/ carers of a patient with a previous admission to critical care in the last five years
3. NHS employees involved in the care of critical care patients in ICU
4. NHS employees involved in the care and recovery of patients discharged from critical care (e. g. physiotherapists,
psychologists, occupational therapists etc.)

Phase 3 feasibility study:
- Adults with capacity to consent
- Current hospital admission involving a stay in critical care, requiring organ support for more

than 48 hours OR the loved one/ relative of someone admitted to critical care and is participating in the Phase 3 study
- FOR ICU PATIENTS ONLY: If normal vocalization is not possible (due to tracheostomy) then the participant must have an established method of communication with bedside nurse/ ward staff

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Previous inclusion criteria:

Phase 1 focus groups:
1. People with a previous admission to critical care within the last five years
2. Family members/ carers of a patient with a previous admission to critical care in the last five years
3. NHS employees involved in the care of critical care patients in ICU
4. NHS employees involved in the care and recovery of patients discharged from critical care (e. g. physiotherapists,
psychologists, occupational therapists etc.)

Phase 3 feasibility study:
1. Adults with capacity to consent
2. Recent (within 4 weeks) admission to critical care requiring organ support for more than 48 hours
3. Any phase 1 participant that wishes to trial the intervention in phase 3 will be allowed to do so

Participant type(s)
Patient, Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40 (20 participants for Phase 1 and 20 participants for phase 3)

Key exclusion criteria
Current exclusion criteria as of 11/10/2024:

Phase 1 focus groups:
1. Any person unable to provide informed consent
2. Any person unable to communicate in English

Phase 3 feasibility study:
- FOR PATIENTS ONLY: Any person experiencing delirium as assessed daily using CAM-ICU
- A history of severe motion sickness
- A history of photosensitive epilepsy

- Any physical or anatomical contraindications to using VR headsets (e.g. severe visual or hearing impairment, major skull or facial surgery). [This does not include those that may require assistance to place the headset due to muscle weakness from ongoing admission.]
- Any person unable to communicate in English

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Previous exclusion criteria:

Phase 1 focus groups:
1. Any person unable to provide informed consent
2. Any person unable to communicate in English

Phase 3 feasibility study:
1. Any person with a recent critical care admission still experiencing ongoing issues with delirium
2. A history of severe motion sickness
3. A history of photosensitive epilepsy
4. Any physical or anatomical contraindications to using VR headsets (e.g. severe visual or hearing impairment, major
skull or facial surgery)
5. Any person unable to communicate in English

Date of first enrolment
17/07/2023

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
The Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
United Kingdom
CF72 8XR

Sponsor information

Organisation
Cwm Taf University Health Board

Sponsor details
Dewi Sant Hospital
Albert Road
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CF37 1LB
+44 1443 443443 ext. 75627
Rhian.Beynon@wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://cwmtaf.wales/

ROR
https://ror.org/00rh52j13

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

We plan to publish the results of the study in the peer reviewed academic literature within one year of study completion. Results will also be disseminated to all study participants directly. Further plans for dissemination will be guided by our public and patient involvement members.

Intention to publish date
31/05/2026

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from ctr@cardiff.ac.uk. All applications for data will be individually assessed by the centre for Trials Research study adoption group. Data will be available for up to ten years following study closure. Consent for de-identified data sharing has been obtained from all study participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Phase 1 version 2.0	14/06/2023	12/07/2023	No	Yes
Participant information sheet	Phase 3 version 2.0	14/06/2023	12/07/2023	No	Yes
Protocol file	version 1.0	03/05/2023	12/07/2023	No	No
Participant information sheet	Phase 1 version 2.1	28/08/2023	14/10/2024	No	Yes
Participant information sheet	Phase 1 HCP version 2.1	28/08/2023	14/10/2024	No	Yes
Participant information sheet	Phase 3 version 3.0	19/08/2024	14/10/2024	No	Yes
Participant information sheet	Phase 3 Family version 1.0	19/08/2024	14/10/2024	No	Yes
Participant information sheet	Phase 3 HCP version 3.0	19/08/2024	14/10/2024	No	Yes
Participant information sheet	Phase 3 Summary version 1.0	19/08/2024	14/10/2024	No	Yes
Protocol file	version 4.0	10/03/2025	13/05/2025	No	No
Protocol article		12/08/2025	15/08/2025	Yes	No