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VR READY: a protocol for a non-randomised, single-arm, mixed methods, feasibility trial of a coproduced *ViR*tual *RE*ality intervention to *AiD* recover*Y* in people recently admitted to intensive care

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ABSTRACT

Introduction Post-intensive care syndrome (PICS) describes a cluster of ongoing symptoms experienced by a large proportion of patients previously admitted to critical care. Despite a large rise in survival following critical care, interventions to support recovery and combat PICS are lacking. It has been suggested that the use of digital tools such as virtual reality (VR) may play a useful role in the development of recovery-supporting interventions. We engaged with people with lived experience of critical care admission to coproduce a VR intervention (*ViR*tual *RE*ality to *AiD* recover*Y* post ICU (VR READY)). Here, we present a protocol for the initial feasibility and acceptability testing of this intervention.

Methods and analysis This is a single-arm, single-site, non-randomised feasibility trial of VR READY. Up to 25 participants recently admitted to critical care will be recruited to use the VR READY intervention for at least 5 min per day for a period of 14 days. Participants must have capacity to consent and be free from ongoing delirium in order to participate. Outcomes relating to sleep and well-being will be measured at baseline and at day 14 after intervention delivery. The primary outcome is feasibility, which will be assessed according to prespecified criteria. Participants will complete a qualitative interview to assess acceptability of the intervention, trial design and outcomes approximately 1 month after completing the intervention period. No formal statistical analysis of outcomes will be conducted, but these will be summarised descriptively. Interviews will be subjected to reflexive thematic analysis.

Ethics and dissemination This study received a favourable ethical opinion by North-East York Research Ethics Committee (Ref 23/NE/0113) in June 2024. Study results will be disseminated through the peer review literature, ISRCTN registry and directly to participants, which will be facilitated by the study public and patient involvement steering group.

Trial registration number ISRCTN88854487.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ *ViR*tual *RE*ality to *AiD* recover*Y* post ICU (VR READY) is a coproduced intervention, using the input of those with lived experience of critical care admission to develop an applicable and acceptable tool for use in people recovering from critical illness.

⇒ VR READY is an adaptation of existing technology where there is some evidence of benefit for its use in closely related context within the host organisation.

⇒ Limits on resource necessitate a single site, single-arm trial, so it is not possible to examine potential barriers to use across broader institutional contexts or estimate potential comparative effects on selected outcomes.

⇒ Similarly, resource constraints prevent longitudinal follow-up beyond the primary endpoint to examine more distal impacts of the intervention.

⇒ This study will assess the feasibility of VR READY as a guided self-help intervention for supporting recovery from a critical care admission, and results will inform the design of future studies, including pilot and subsequent effectiveness trials.

BACKGROUND AND RATIONALE

Advances in knowledge alongside the implementation of new therapeutic interventions in intensive care medicine have led to an improvement in the survival of those experiencing critical illness. However, despite this improvement, those surviving critical illness can experience a myriad of ongoing health problems, which persist beyond discharge from secondary care settings.[1] The cluster of physical limitations, cognitive issues and psychological problems experienced by critical care survivors is more commonly known as postintensive care syndrome (PICS).[2] PICS significantly affects patients and their families, with far-reaching consequences on quality of

life; a significant proportion of patients requires additional assistance 12 months postdischarge.[3 4] Additionally, there is evidence to indicate that increased, persistent and negative psychological sequelae remaining after discharge from critical care are associated with increased mortality[5] (https://www.mdpi.com/2077-0383/11/18/5257).

Gold standard interventions implemented in the ICU for PICS prevention exist and include the choice of sedation drugs, sedation breaks, spontaneous breathing trials, early mobilisation, promotion of sleep, optimisation of nutritional support and psychological support.[3 6 7] However, standardised approaches to supporting recovery beyond hospital discharge are lacking; variable numbers of patients in the UK receive dedicated follow-up within 3 months of hospital discharge.[8 9] The lack of consistent approach to recovery and rehabilitation has numerous, serious implications both for the health of patients and impact on healthcare systems[10] and is a priority area for new research initiatives, emphasised in the UK guideline for the provision of intensive care services (GPICS2).[11] The GPISC2 guidelines further recommend the ongoing monitoring of appropriate outcomes, with individual rehabilitation plans to support recovery; yet only a small percentage of sites routinely provide this standard of care.[12] The lack of guideline adherence is underpinned by a lack of staff or financial resources. Consequently, it has been suggested that alternative strategies for delivering appropriate interventions such as virtual platforms and home-based care should also be explored.[8] Furthermore, the GPICS2 recommendations for rehabilitative interventions emphasise the need to include multidimensional elements covering physical, functional, communication, social, spiritual, nutritional and psychological elements.[11]

A potential novel intervention to promote recovery in critical care survivors could be the use of immersive virtual reality (VR) platforms. The use of VR has already been trialled in a variety of healthcare settings, demonstrating promise in a range of clinical areas.[13–16] With particular reference to intensive care settings, the use of VR has demonstrated benefits in reducing pain and anxiety, help with relaxation while being safe and acceptable to patients.[17]

In response to the literature, we wanted to investigate the utility of immersive VR for reducing the incidence and subsequent symptoms of PICS in those who had experienced critical care. The initial intention was to coproduce a home-based, VR-mediated intervention, based on the experiences and recovery priorities of critical care survivors, which would be used relatively soon following hospital discharge. This would involve adaptation of the content of an existing VR device, DR.VR.[18] However, following a programme of consultation with those with lived experience (manuscript in preparation), the timing of intervention delivery switched from postdischarge to something delivered within the hospital stay that could also accommodate at-home use. The people with lived experience wanted an intervention designed to improve the psychological impact, and subsequently other areas, they felt had an impact during their hospital stay that persisted into the transition back home.

Following the coproduction of the VR intervention, called VR READY (*ViR*tual *RE*ality to *AiD* recover*Y* post ICU), we wanted to test its feasibility and acceptability within the critical care setting. People admitted to critical care experience significant issues with fatigue and physical ability, so it is important to determine how feasible it is to collect a range of outcome measures within this setting. We want to determine the feasibility and acceptability of the outcome measures selected, trial processes and obtain detailed user feedback on VR READY to understand how further evaluation, leading up to fully powered effectiveness trial, would need to be designed. Additionally, given that VR may represent a tool with low healthcare professional (HCP) resource requirements to support recovery, we also wanted to explore how the adaptation of DR.VR may be suitable for other healthcare conditions and in other healthcare contexts. Here, we present a protocol for the VR-READY trial, where the data collected will inform the design and implementation of further effectiveness studies to investigate the use of immersive VR to support recovery of people admitted to critical care.

METHODS

Public and patient involvement

From the outset, this trial has involved those with lived experience in its development and design. The trial team includes a public and patient involvement (PPI) coapplicant, who is part of the trial management group, attending monthly meetings and providing PPI oversight of the trial. The intervention being evaluated was coproduced with those with lived experience of a critical care admission via a series of focused group discussions (manuscript in preparation). Briefly, an iterative series of focus groups were held with critical survivors and HCPs involved in their care to understand the recovery journey. Priorities for recovery were determined and working with our PPI steering group, we discussed the content they believed would be useful to promote recovery in critical care patients. The main input of this group was to amend the target of the intervention from the postdischarge, at home recovery period, to an in-hospital intervention. Latterly, this PPI steering group was involved in the codesign of the protocol, informing recruitment population, the timing of the intervention, outcome measures included, identifying key cost drivers and the timing of assessments. The group remains engaged as a PPI steering committee to comment on the feasibility trial progress, analysis of the qualitative evaluation and will be instrumental in the dissemination of the feasibility trial results.

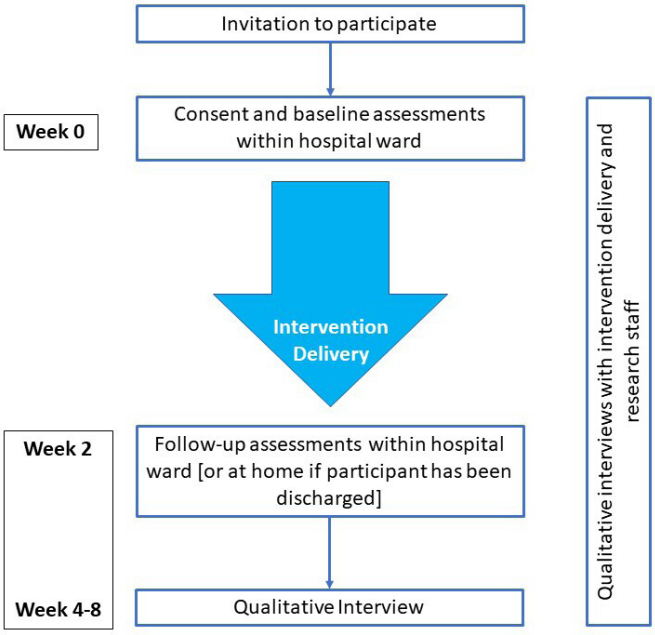

Figure 1 Schematic of the *ViR*tual *RE*ality to *AiD* recover*Y* post ICU (VR READY) feasibility trial design.

Trial design

The VR READY intervention will undergo evaluation in a single-site, single-arm, non-randomised, non-blinded feasibility trial with up to 25 participants admitted to critical care with an intervention delivery period of 14 days. Our primary focus was on assessing the feasibility and acceptability of the intervention, which can be addressed adequately through the single-arm design. Resource constraints restricted delivery of a trial with a second comparator arm and randomisation. Family members and support partners of patients admitted to critical care will be able to take part in the trial if they so wish but will not contribute to the main sample size. The sample size of 25 participants is consistent with previous work,[19 20] suggesting that a sample size of 12–25 is appropriate for feasibility studies. In addition to the measurement of outcomes (outlined below) before and after the 2-week intervention, we will also conduct a process evaluation of the trial to understand the contextual and logistical elements of intervention delivery and evaluation (see figure 1), which will include the recruitment of trial delivery staff.

Objectives

The primary objective of this trial is to determine the feasibility and acceptability of the VR READY intervention in an acute hospital setting. Secondary objectives of the trial include:

1. determining the feasibility and acceptability of the selected outcome measures for use in future effectiveness and cost-effectiveness studies for ICU recovery and
2. to generate a framework for DR.VR adaptation that can be applied to other healthcare and at-home settings.

Trial setting

This trial will be conducted within the critical care unit or within a general ward in the first few days of step down from critical care, in a district general hospital in South Wales, UK. This is a general medical and surgical intensive care unit with 12 beds used flexibly for levels 2 and 3 support. The main specialties from which patients are admitted to the ICU include colorectal surgery, head and neck surgery, urological surgery, general medicine, respiratory medicine, endocrine, gastroenterology, hepatology, cardiology and stroke service. Intervention delivery will commence in either critical care or the high dependency unit and following the patient pathway may continue in other wards within the hospital or at home.

Eligibility criteria

To be eligible to take part, participants must satisfy all of the inclusion criteria and none of the exclusion criteria. The inclusion criteria for critical care patients comprise of (1) adults with capacity to consent, (2) participants experiencing a current hospital admission involving a stay in critical care, requiring organ support for more than 48 hours and (3) if normal vocalisation is not possible (due to tracheostomy) then the participant must have an established method of communication with bedside nurse and/or ward staff. For family members, the only inclusion criterion is if they are the loved one/relative of someone admitted to critical care who is already participating in the trial.

The exclusion criteria for critical care patients and their family members include (1) history of severe motion sickness, (2) history of photosensitive epilepsy, (3) any physical or anatomical contraindications to using the VR headset (eg, severe visual or hearing impairment, major skull or facial surgery) and (4) any person unable to communicate in English. There is an additional exclusion criterion for critical care patients only which is experiencing delirium as assessed daily using the Confusion Assessment Method for the ICU.

There is no specific criterion for inclusion/exclusion relating to the trajectory of illness of the participant because this trial focuses on initial feasibility and we did not want to be overly restrictive with eligibility criteria in an effort to promote broad inclusivity.

HCPs involved in any degree of delivery of the trial at site, including intervention delivery and outcome assessment, will be included in the process evaluation.

Recruitment and participant consent

All participants (critical care patients and their family members if wanting to take part, plus HCPs involved in trial delivery) will be required to provide written informed consent prior to inclusion and any data collection (an example consent form can be found in supplementary material). Consent will be obtained by either the site principal investigator or suitably qualified (Good Clinical Practice (GCP) and trial trained) members of the research team who have been delegated responsibility.

This may include research officers, nursing staff or other allied health professionals. If the participant struggles to hold a pen, then a witness may sign the consent form on their behalf, with appropriate documentation in the participant's medical notes.

HCPs involved in trial delivery will be invited to take part in the process evaluation. They will receive study information and be informed that they can make a decision to take part or not without prejudice to their employment. Prior to the start of their interview, they will complete consent online. This will include recording their verbal consent plus completion of a digital consent form, which is then emailed to the trial team.

Intervention

The VR READY intervention is an adaptation of the VR content of DR.VR (https://www.rescape.health/why-vr), which is a CE Marked Class I medical device, approved for application in healthcare settings as a tool to improve psychological well-being. We worked with people with lived experience of a critical care admission to develop bespoke content to support the recovery of people undergoing critical illness primarily through psychological support. Initially, we had envisaged developing an intervention that would support ongoing recovery following hospital discharge (to be implemented around the 3-month mark), but the PPI feedback received was that an in-hospital intervention to address the immediate impacts of critical illness would be more valuable. The PPI contributors felt that addressing the psychological impact of a critical care admission early on in the recovery process would enable greater self-management of the recovery journey. Subsequently, the content developed was focused on supporting mental well-being and providing information and simple meditative exercises that participants could engage with to support self-management of recovery.

VR 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 six different immersive environments with simple narration to introduce the user to that environment and invite them to explore the setting. The different settings in this section are (1) 'underwater'—an exploration underwater featuring marine life; (2) 'cities'—a guided exploration of a busy city scape; (3) 'travel'—an opportunity to experience a range of different worldwide locations; (4) 'wild hikes'—a wild hike off the beaten track exploring a variety of landscapes; (5) 'wildlife'—an up close and personal experience with some of the world's most endangered animals and (6) 'space'—an exploration of the solar system.
2. Mindfulness and motivation—contains six exercises to promote mindfulness and provide motivation for recovery. Individual exercises include (1) 'virtualisation for motivation'—a bespoke 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; (2) 'sleep'—a guided relaxation experience to promote recentring and relaxation; (3) 'mindful seeing'—a session that teaches how to look mindfully at the world; (4) 'body scan'—'a mindfulness session to reduce anxiety and stress through connecting with your body; (5) 'calming mind'—a session that involves watching the ripples of water in a lake calm the mind and bring perspective to your thoughts and (6) 'mindful listening'—'a session that supports listening to the world around us, learning to stop and be within the moment'.
3. Breathing—this section contains the original breathing exercises featuring in DR.VR modified in terms of their speed and tailored to the expected capabilities of the participant population. This entails three computer-generated scenes (beach, snow and forest) with accompanying soundscape where the user is guided through a breathing exercise.
4. Information—this contains a number of information videos featuring key staff roles (psychologist, occupational therapist, dietician, speech and language therapist, physiotherapist) encountered by patients when they are admitted to critical care. The videos simulate the specialist coming to see the viewer in a hospital environment to explain their role and why the patient might interact with them.

Example stills of the type of content are seen in figure 2.

Following completion of baseline assessments, participants will be provided with a VR headset and instructed on how to use the equipment by a member of the

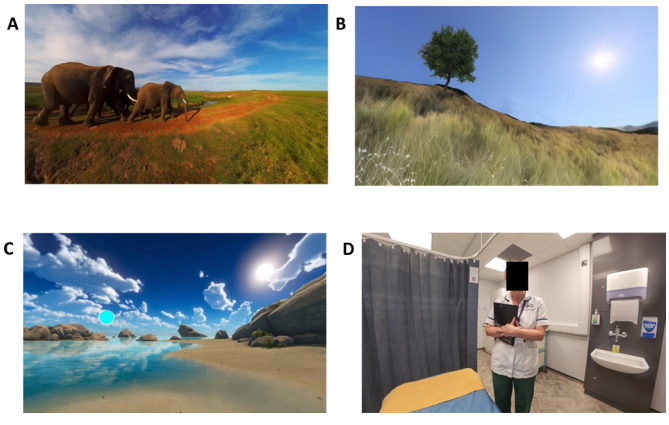

Figure 2 Representative stills taken from the VR READY user interface. Here we see examples of the user interface from the exploration section, featuring a wildlife encounter with a herd of elephants (A) the mindfulness and motivation section where users are guided through a motivational experience set in a countryside environment (B), the breathing section where users are guided through breathing exercises in a relaxing beach setting (C) and the information section where individuals working in critical care introduce themselves and their role to users (D).

research team (members of the research team include HCPs involved in the care recovery support of critical care patients). The VR headset then remains solely with that participant for the full length of the intervention delivery period. A written instruction manual will also be provided. For at least the first 2 days of the 14-day intervention period, the participant will be assisted by a member of the research team to guide use of the VR apparatus, troubleshoot any problems with use and ensure that the participant is not experiencing any undue problems from using the headset. Beyond this, if the participant continues to struggle with using the apparatus independently (ie, through muscle weakness) then a member of the research team will be available daily to assist. HCPs caring for the patient may also assist the patient if they feel confident to do so and have been trained by the study team. Alternatively, if participants are being regularly visited by family members, we will not prevent the family members from assisting participants to use the VR intervention. During the intervention delivery period, participants will continue to receive all usual care as directed by the clinical team. Participants will be asked to engage with the VR content for at least 5–10 min a day. This is consistent with current literature that suggests this is sufficient time for people to benefit from the VR environment. Participants will be introduced to the content available at the first session and will be left to explore the full range of the content individually. Participants are at liberty to choose the nature of the content they wish to engage with. This may involve exploring all content options available to them via the headset or more targeted use of specific sections. Beyond the introduction to what is available, participants will not receive further guidance on what content they should engage with.

If a participant is discharged to home during the 14-day intervention delivery period, they will be loaned the headset to complete the intervention period. The headset will then be collected from the participant by a member of the research team. Usage data recorded on headset include the duration of use and identification of content accessed and will be downloaded at the end of the intervention period to assess adherence.

Any family members/loved ones interested in taking part in the trial will be provided with the VR READY intervention as described above. However, following this initial introduction to the equipment, they will not receive daily additional support. The family member may take the VR headset home with them to continue use for the 14-day intervention period.

Outcomes

The primary outcome of the trial is feasibility as defined by recruitment, retention, data completeness and intervention adherence. Each feasibility criterion will be assessed against the predefined thresholds outlined in table 1. For the trial to be deemed feasible and suitable to progress to an effectiveness trial without modification, all progression criteria must meet the green threshold. If one or more measures meet the amber threshold, then modifications to the trial design should be considered prior to progression to an effectiveness trial. If one or more criteria fall within the red threshold then it would be deemed unfeasible to conduct an effectiveness trial.

Secondary outcomes for the trial include evaluation of technology acceptance (willingness and ability of participants to engage with VR as a technology), and acceptability of the intervention (understanding participants' views on the content of VR READY and its use within the hospital (and at home if applicable) setting), outcome measures and trial processes, forming an embedded process evaluation of the trial. Outcome measures listed below and in table 2 will be assessed at baseline and at 14 days following the intervention. The process evaluation will involve qualitative interviews with all participants between 2 and 6 weeks after completion of the intervention (table 2).

Specific clinical outcome measures were selected in conjunction with the PPI steering group to assess the desired effects of the intervention (namely psychological well-being and quality of life). The PPI steering group was asked to specify which domains surrounding recovery were most important to them, and identified sleep, mood and general well-being as key elements contributing to recovery. The trial team presented a range of potential outcomes that could be used to assess these domains. Final selection of outcome measures was made by prioritising relevance, overall time to complete, relevant timeframe of assessment, complexity and total number of individual items.

Table 1 Criteria for assessing feasibility outcomes

Variable		Progression criteria		
		Red	Amber	Green
Recruitment	Number of screened actually recruited	<5%	5–19%	20%
	Number of approached willing to participate	<50%	50–74%	75–100%
	Number of recruited	<6 in total	6–12	12–25
Retention	Number of partially active trial participants at primary end point	<50%	50–79%	80%
Adherence	Completion of intervention sessions	<50%	50–79%	80%
Data completeness	Completion of baseline measures	<50%	50–79%	80%
	Completion of follow-up measures	<50%	50–69%	70%

Table 2 Timeline of participant assessments

Procedures	Visits				
	Screening (–5 days to –1 day)	Baseline (day 0)	Intervention delivery (day 0–14)	Follow-up Day 14 (± 2 days)	Day 28–54
Informed consent		x			
Demographics		x			
Eligibility assessment	x				
Brief Resilience Scale		x			
EQ-5D		x		x	
ICECAP-A		x		x	
RCSQ		x		x	
DASS-10		x		x	
VR READY intervention delivery			x		
Intervention adherence			x		
Qualitative interviews					
Participants					x
Intervention delivery staff			x		

DASS-10, Depression and Anxiety Scale [10 item]; EQ-5D, EuroQoL 5 dimensional questionnaire; ICECAP-A, ICEPop Capability Assessment for Adults; RCSQ, Richard Campbell Sleep Questionnaire; VR READY, *ViR*tual *RE*ality to *AiD* recover*Y* post ICU.

Brief Resilience Scale[21] is designed to assess psychological resilience and will be employed to describe the recruited cohort. The measure consists of 6 items relating to response or coping to adverse life events. Participants are asked to rate each statement from strongly disagree to strongly agree, which is then scored between 1 and 5 depending on the direction of the question. Responses are averaged to provide an overall score. A higher score reflects a higher degree of resilience. This questionnaire has been demonstrated to have good internal consistency and has high validity across several populations[22–24] with the resilience factor assessed associated with well-being.[25]

EuroQol-5 D[26]—a validated outcome measure for assessing health-related quality of life over five domains, which has excellent psychometric properties across a range of populations and settings[27]; usual activities, self-care, mobility, anxiety and depression, and pain and discomfort. Participants are asked to select one of five statements that most applies to them. Participants are also asked to rate their overall quality of life using a visual analogue scale (0–100). Each statement is scored according to the corresponding level (1–5) to produce a five-digit health state, which can be summarised to provide an index value, which can be used to calculate quality-adjusted life years for use in cost-utility analysis.[28]

ICEPop Capability Assessment for adults[29]—a validated well-being/capability instrument comprising of five conceptual attributes covering: attachment, stability, achievement, enjoyment and autonomy. Participants are asked to agree to one of four statements within each attribute. Each statement is scored 1–4, with four being the top level and representing full capability within the conceptual attribute. To score, each level within an attribute has an individual tariff. The sum of all five tariffs provides the overall score, which can be used to calculate a cost per year of sufficient capability well-being.[30] This measure is reliable with strong construct validity and ability to detect differences between groups[31 32] and is regarded as complementary to other health-related quality of life measures as it assesses a specific aspect of well-being.[33]

Richard Campbell Sleep Questionnaire—a 6-item questionnaire specifically designed to address sleep and sleep quality in critical care patients. Participants are asked to respond to each item on a scale of 0–100 (with 100 representing the most positive score). Items included cover; sleep depth, latency, awakenings, ability to return to sleep, sleep quality, with an optional item concerning noise. The measure displays good reliability and internal consistency, underpinning its validity for assessing sleep quality in this population.[34]

Depression Anxiety Stress Scale[35] is a shortened, 10 item version of the full-length 42 item questionnaire designed for routine monitoring of outcomes in usual psychology practice to provide an overall measure of distress. Participants rate items from ‘never’ (0) to ‘almost always’ (3), which are used to produce a total score. This measure correlates with other measures of anxiety, depression and stress and has demonstrated sensitivity to change, making it useful and valid measure for monitoring the effects of interventions.[35]

Data collection and management

Outcome measures will be assessed at baseline and again after the 14-day intervention delivery period (see table 2). Baseline outcome measures will be completed in hospital at the participant bedside. Follow-up outcome measures

will also be completed in hospital if the participant is still an in-patient, or at home if they have been discharged. Participants will be asked for their preferred mode of data collection; on paper forms, direct electronic data capture into the trial database (REDCap) or completion via telephone with the support of a researcher. Additionally, if in-patient participants struggle to complete the outcome measures independently, they may be facilitated by a trial researcher by reading them the statement question and all possible response options, allowing the participant to indicate their response. All data will be labelled with a unique alpha-numeric identifier. All data will be entered into a REDCap database, which contain in-built validations to prevent erroneous data entry. Where data are collected on paper CRFs, data will be entered by the trial research officer. Prior to database lock, a random selection of 10% of CRFs will be reviewed against data in the database to ensure accuracy of data entry. All data management processes will be detailed in the trial data management plan.

Semistructured qualitative interviews for the process evaluation will be held in person, via telephone or online using secure video-conferencing software, such as Microsoft Teams, dependent on participant preference. Interviews will be conducted by a qualitative researcher within the study team. Intervention delivery staff (at least one is also a member of the research team) will also be interviewed during the recruitment and intervention delivery period. Interviews will be structured based on the Unified Theory of Acceptance and Use of Technology[36] as a framework. Data from the process evaluation will be combined with outcomes of the intervention codevelopment part of the wider study (published separately) to develop a framework for DR.VR adaptation across other healthcare contexts.

Safety and harms

This is a low-risk intervention, and additional harms are not anticipated. However, participants will be monitored for adverse events. For those participants still in hospital, they will be visited by a member of the research team each day as part of intervention delivery and adverse events will be monitored at each of these interactions. Participants discharged home during the intervention delivery period will be advised to report any adverse events to the research team. The follow-up interview will also include questions around adverse events.

Participant withdrawal

Participants will have the right to withdraw from any part of the trial (intervention, assessments or process evaluation) at any time without adverse consequences. Data collected up until the withdrawal of consent will be retained unless the participant specifies that they want it to be destroyed. Participants will be asked, but not obligated, to provide their reasons for withdrawal. These will be summarised for inclusion in the feasibility assessment.

Analysis

No formal hypothesis testing of outcomes will be undertaken as part of the analysis. The primary outcome of feasibility will be assessed according to the predefined criteria specified in table 1. The percentage of people approached willing to participate in the trial, the percentage of people screened who are then successfully recruited to the trial and the total number of people recruited to the trial will be calculated from interrogation of the site-screening log. The number of participants partially active in the trial will be determined through scrutiny of withdrawal forms and through the completion of outcome measures at follow-up. The percentage completion of baseline and follow-up measures will be calculated as both; number of outcome measures completed against those expected and the number of data points completed across all measures against those expected. For analysis of adherence, usage data will be downloaded from the VR headsets and a total usage figure (in minutes) will be calculated for each day. The daily usage figure will be determined as being adherent if this is more than 5 min in total. The number of days each participant meets the adherence threshold will be calculated and the percentage adherence across the 14-day intervention period will be calculated as the number of days the participant was adherent (ie, used the intervention for 5 mins or more) as a percentage of the total number of days (14) the intervention was to be used across.

The analysis of acceptability will be qualitative in nature. Recordings of qualitative follow-up interviews will be transcribed verbatim. Transcripts will be subjected to analysis using an a priori framework based on the Unified Theory of Acceptance and Use of Technology[36] and a mapping approach followed by a thematic analysis informed by Braun and Clarke[37] and Adu[38] using NVivo software as a data management tool.

Clinical outcome measure data will be collated, analysed descriptively using means and SD and summarised in a tabular format. This will be triangulated with the interview data using a mixed methods approach[39] to complement their qualitative evaluation.

The cost of the VR READY intervention will be assessed in terms of the costs of equipment, staff training and time to train participants. Key cost drivers identified in the focus groups will be described to define the perspective for costing in an economic evaluation alongside a full clinical trial, for instance, only health and social care costs or including wider personal costs.

ETHICS AND DISSEMINATION

The VR READY study received an initial favourable ethical opinion by North East York Research Ethics Committee (REC) (Ref 23/NE/0113) on 16 June 2024. A substantial amendment was submitted to account for changes made during the earlier intervention development process that affected this specific feasibility trial (protocol V.3.0 date 19 August 2024) and this received a favourable opinion

4 October 2024. This amendment included the changes made to the DR.VR content, the change in outcomes measures to be assessed, the setting for delivery of the intervention (from at home to in-hospital) and the time frame for follow-up. A non-substantial amendment (protocol V.4.0 10.03.2025) was made to increase target recruitment to 25. Any subsequent protocol amendments will seek relevant REC and Health Research Authority approvals prior to implementation at site.

Recruitment commenced on 24 October 2024 and will continue until 30 April 2025.

Results of this trial will be published in the peer-reviewed literature and at relevant clinical conferences. Our PPI steering group will be involved in the production of a plain English summary and easy-read infographic for dissemination to trial participants, for the ICU survivor community and broader publics.

Data sharing

Quantitative data will be made available on request to the sponsor organisation. Access to qualitative data will be limited due to the small numbers involved and potential for re-identification of de-identified transcript.

Trial governance

This trial is sponsored by Cwm Taf Morgannwg University Health Board (CwmTaf.R&D@wales.nhs.uk). The sponsor will be independent from trial design, data collection, data analysis and interpretation of data, but they will contribute to trial conduct. The trial will be overseen by a trial management group (including all authors) that convenes monthly to monitor progress and trial conduct. In this low-risk, single-arm, non-blinded trial, no formal trial steering committee or independent data monitoring committee will be convened. Data will be monitored centrally by members of the research team (not involved in recruitment or data collection), beyond this, there will be no formal onsite monitoring.

Trial status

The trial opened to recruitment in October 2024 and completed in April 2025.

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