ViRtual REality to AiD recoverY post-ICU
VR-READY

PARTICIPANT INFORMATION SHEET

What is the study about and why are we doing it?
People who have been admitted to intensive care (ICU) for a long time often report ongoing problems with everyday physical functions, thinking and anxiety after they have come home from hospital. Collectively this is known as Post Intensive Care Syndrome or PICS and can stop people resuming their normal activities. Although limited NHS services exist in some areas to help people recover following a stay in ICU, there are no standardised national programs which are specifically aimed at promoting recovery in those with PICs. With the recent increase in people being admitted to ICU and therefore experiencing PICs, there is a real need to find ways of helping these people get better and achieve a good quality of life.

Virtual Reality (VR) describes a process where a head set transports users to a computer generated 3-dimensional environment. VR has shown promise in treating problems with mental health and psychological disorders (such as anxiety and stress) and we think that VR may be useful for treating PICs. We have co-developed a VR based intervention (a program or tool that can be used to change a particular outcome) with patients with lived experience of PICS and their family members. This uses a VR headset containing VR programs that can be enjoyed by the user, together the VR equipment is known as DR.VR. The aim of the intervention is to support the recovery of people recently discharged form ICU. We now want to test this intervention in a small number of people who have been recently discharged from ICU. The aim of this testing is to see if the VR intervention we have developed is easy to use and if people recently discharged from ICU are happy to use the VR intervention at home. We also want to understand how best to measure how well the VR intervention may or may not work as well as understand what is needed to deliver the intervention.

Why am I being invited to take part?
We understand that you have recently returned home following a stay in intensive care. We would like people who have recently been in intensive care and have now returned home to continue their recovery to test the VR intervention we have developed in their homes.

What would taking part involve?
You do not have to take part in this study if you do not want to. A decision to not take part will not affect your medical or legal rights in any way. If you do make a decision to take part in this study, you will be asked to come to the Royal Glamorgan Hospital for a study visit. At this first visit, we will ask you to complete some questionnaires to make sure that you are suitable to take part in the study. We will also ask you to complete some additional questionnaires so that we can understand where you are in your recovery journey. You will be given the option to complete these questionnaires on-line or on paper and support will be provided to complete them if you need it.

You will then be given a DR.VR headset to take home as well as instructions on how to use it. You will be shown how to use the headset and interact with the VR program before you go home and you will be able to ask any questions about the DR.VR headset that you need to.

Once you go home you will be asked to use the VR headset <insert details of use here after decided by Phase1/2 activities> for a period of <insert time frame decided following Phase1/2 activities, likely to be 8-12 weeks>. You do need to have Wi-Fi at home to be able to use the DR.VR headset. The DR.VR headset stores information about how much you use the headset and which activities you engage with, which we will collect at the end of the study, however, it does not store any information about you.

If you have any problems using the headset or completing the tasks as set-out in the instruction booklet, you can either e-mail the study team or call the study research nurse (contact details for both are at the end of this information sheet).

After you have completed the 8 weeks of using DR.VR we will ask you to answer the same questionnaires that you did at the beginning of the study, but at home. Again, you will have a choice of completing this on paper or on-line and with support if required.

When you have completed the questionnaires, a researcher will contact you to arrange a convenient time for an interview. This can take place in your home or any other location that you are comfortable with. The interview will be to discuss your experiences of using the VR intervention and about the questionnaires we asked you to complete. We expect that this will take around an hour to complete. When the interview is over, the researcher will collect the DR.VR headset from you. We are unable to provide you with a DR.VR headset beyond the duration of this study.

What are the possible risks and benefits of taking part?

There are unlikely to be any direct benefits of you taking part in this study, however, you may enjoy using the DR.VR headset. Some previous studies have shown that using VR can help reduce stress and anxiety, and we hope our intervention may have a similar effect, but this is not guaranteed.

We will take steps to ensure that you are safe to use the VR headset and software and will advise you not to take part if you have any condition that is affected by flashing lights or if you have a history of severe motion sickness. The DR.VR headset is a CE marked medical device, which means it has been approved as being safe to use in people, so we do not expect there to be any risks with using it.

If you find any part of taking participating in this study distressing, we can arrange for you to talk with the study team's clinical psychologist who can provide support or signpost you to appropriate support where necessary.

Will I be paid to take part?

You will not be paid to take part in the study, but we will cover any travel expenses that you may incur in order to attend study visits. This may mean sharing your personal data with the finance department.

What will happen if I don't want to carry on with the study?
You can stop taking part in the study at any time without your medical or legal rights being affected in any way. You can decide to stop taking in part in the intervention only, or from all parts of the study. If you do decide to withdraw from the study, we will keep information gathered from you during the study unless you specifically request that we do not.

How will we use information about you?
We will need to use information from you for this research project. This information will include your name, contact details, ethnicity, age and information about your health and quality of life. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. .
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- at Cwm Taf Morgannwg University Health Board's privacy notice https://ctmuhb.nhs.wales/use-of-site/privacy-policy/
- by sending an email to Cwm Taf Morgannwg University Health Board's data protection officer Claire.northwell-todd@wales.nhs.uk

How will my information be kept confidential?
We will take steps to ensure your confidentiality at all times. Only people working on the study will have access to the data. This includes members of the team who work outside the health board. Please be aware that if you contact the study email address (found at the end of this document) that will be sharing your personal data outside the direct health care team. When you are enrolled in the study, you will be assigned a unique study number which will be used to label any data associated with you. No personally identifiable data will be used or stored alongside the study data. The data we collect, including the audio recordings and written records of the interviews will be stored securely for the duration of the study and for up to 10 years afterwards, after which time they will be securely destroyed in line with Health Board policy. The written records of the interviews will be changed to make sure that you

cannot be identified from them. These data will be used for analysis and we may want to use direct quotations from them when we share the results of the study (see section on 'What will happen to the results?'). We will only do this with your express permission. We will keep your contact details for up to three years so we can share the results of the study with you.

The data collected about you during this study may be shared with other academic and non-academic researchers either within the UK or outside the UK. This will only be done for the purposes of healthcare and public health research either as part of this study or for future research. We will take steps to make sure that you cannot be identified by name by sharing the data (pseudonymised).

All information collected about you during this study will be kept confidential and will be handled, stored and destroyed in accordance with the General Data Protection Regulation.

What will happen to the results of this study?
The results of VR-READY will be shared with the people who took part in all aspects of the study once it has been completed. The results will also be shared with health care professionals and other researchers at national and international conferences and in peer reviewed journal articles. The results in the study may include data specifically from the interviews and may include direct quotations from you. If this happens, we will take steps to make sure that you cannot be identified from these quotations.

Who is responsible for looking after my information?
Cwm Taf Morgannwg University Health Board (CTM UHB) is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. Cardiff University will act as a data processor, with access to personal identifiable data. CTM UHB is responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained, unless you ask us not to. To safeguard your rights, we will use the minimum personally-identifiable information possible.

If you would like more information about the use of personal data for research, visit: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact Cwm Taf Morgannwg University Health Board's Concerns team on 01443 744915 or cthb_complaints@wales.nhs.uk. If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

What happens if there is a problem?

Complaints:

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (contact details are at the end of this information sheet). If you remain unhappy and wish to complain formally, you can contact Cwm Taf Morgannwg University Health Board's Concerns team on 01443 744915 or cthb_complaints@wales.nhs.uk..

Harm:

If something does go wrong and you are harmed during the research which is as a result of someone's negligence, you may have grounds for a legal action against Cwm Taf Morgannwg University Health Board but you may have to pay your legal costs.

Who is organising and funding the research?

This study is being organised by researchers from Cwm Taf Morgannwg University Heath Board and Cardiff University. The Chief Investigators are Dr Ceri Lynch, Dr Kim Smallman and Dr Cheney Drew. The study is being funded by Health Care Research Wales.

Who has approved the research?

All research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and approved by North East - York Research Ethics Committee research ethics committee (REF 23/NE/0113)

What do I do now?

Please take time to consider whether you are willing to take part in this study. Discuss it with others if you wish, and please contact us for additional information or explanation of the information in this document.

If you decide that you want to take part, then simply complete the enclosed contact form and return it to us in the pre-paid envelope provided. Alternatively, you can contact the research team at VRReady@Cardiff.ac.uk to let us know that you want to take part.

Contact Details:

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✉ **VRReady@cardiff.ac.uk**

Thank you for considering taking part in this study.