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 are interested in developing a VR based intervention (a program or tool that can be used to change a particular outcome) aimed at improving recovery in people with PICs. In order to do this, first we need to understand what the term 'recovery' means to different people. We plan to do this by talking to small groups of health care professionals (known as a focus group) and asking them about their experiences in supporting the recovery of people once discharged from ICU. We will also be conducting similar focus groups with ICU survivors. We will use this information to create a VR program to help people recover following an ICU stay. Eventually we will test this is in a small number of people to see how well it might work in practice.

Why am I being invited to take part?

We understand that you or someone you know or care for was a patient in ICU and has experienced some of the problems associated with PICS. We would like people with this experience to contribute to our focus groups so we can get a wide range of opinions about what 'recovery' means to different people and how we might act to improve that for people. 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.

What would taking part involve?

We are planning to hold a series of four focus groups across 4-6 months at the head office of Rescape Ltd in Cardiff. Each focus group is expected to last between one and two hours. Rescape are the company behind the VR headset and software (known as DR.VR) that we plan to adapt to create the VR intervention. We will be working with their software designers to adapt the current DR.VR software to create a VR package aimed at helping people recover after a stay in intensive care.

Each focus group will have between five and eight people, with facilitators from the research team to guide the conversation. All focus groups will be audio recorded and those recordings will be written down so that they can be analysed.

In the focus groups the facilitators will ask you to take part in a number of different activities. This will include describing what recovery after intensive care was like for you or your family member and thinking about what aspects of that recovery journey are most important to measure to show that a person is getting better. You will receive a payment of £50 for each focus group that you attend, and your travel costs will also be paid back to you for each visit. This will mean sharing your personal information with members of the finance department.

Once the focus groups have been completed, you can stay involved in the study, if you want to. We would like people to help us create a special VR software package specifically aimed at supporting recovery in people who have been discharged from ICU. This would be on an entirely voluntary basis, and you would not receive additional payment for your time.

What are the possible risks and benefits of taking part?
Taking part in the focus groups is unlikely to provide any benefit or pose any risk to you. The discussions are likely to include you/ your loved ones experiences of being in ICU, which may involve recounting memories that are difficult or painful. You will not be obliged to share anything that makes you feel uncomfortable- the information you share will be completely up to you and will not affect your participation in this project in anyway. Alternatively, you may find it useful to talk about and share your experiences with other people who have gone through a similar experience. If you find the process 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.

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, or those of your family member, being affected in any way. If you do decide to withdraw from the study, we will keep information gathered from you during the focus groups for analysis 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 and contact details and experiences of being in intensive care. 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
- 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.

The audio recordings and written records of the focus groups will be stored securely for the duration of the study and for up to a year afterwards. The written records of the focus groups 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 direct quotations from the focus groups 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 remainder of the data collected for the study will be stored for up to 10 years, after which time they will be securely destroyed in line with Health Board policy. No personally identifiable data will be used or stored alongside the study data.

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 focus groups 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).

Who is organising and funding the research?
This study is being organised by researchers from Cwm Taf Morgannwg University Health 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/NE0113)

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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Thank you for considering taking part in this study.