Manchester University
NHS Foundation Trust

University of Salford MANCHESTER

Participants Information Sheet: RSVR Participant

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Cardiology Research Department
Wythenshawe Hospital
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Study 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.

(**Title in simple terms**). We're doing a small research study to test if using Virtual Reality can help people feel more relaxed and less stressed before and after their heart surgery. We want to see if this can make their experience better, for those who are having their first planned heart surgery.

Sponsor's Name: The University of Salford
IRAS ID:

You are being invited to take part in a research study. Before you decide whether to participate, you need to understand why this research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

If you have any questions, or would like more information on this project, or your role in it. Please contact the researcher Prof. Bhuvaneswari Krishnamoorthy on the email ID provided (b.bibleraaj@salford.ac.uk).

What is the purpose of this research?

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 have not 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.

In this small-scale research project, we're going to use special VR goggles to create lifelike virtual worlds for adults who are having their first planned heart surgery. We want to see how this VR experience affects their time in the hospital. Our main goal is to figure out if it helps people feel less anxious and stressed, and if it makes their overall hospital stay better. To do this, we will compare two groups of patients.

Why have I been asked to take part?

The study will be conducted at Manchester University NHS Foundation Trust, Wythenshawe site as a single centre. We will invite all first-time patients who are undergoing Coronary Artery Bypass Grafting (CABG) (heart bypass) surgery, Mitral or Aortic valve surgery or combination of these surgeries at Wythenshawe hospital to participate.

Do I have to take part?

Your participation is entirely voluntary, and it is up to you to decide whether or not to take part. We speak to you about this study and give you an information sheet and a consent form in the preoperative ward if you have been admitted as an urgent in patient. You will be given at least 24 hours to consider whether to take part or not in the study, in this time if you have any questions, please contact the research team. If you do decide to take part, it will be valuable for us to understand the effects of immersive virtual reality effects on your stress and anxiety levels before and after the surgery.

What data will be collected if I take part?

All clinical data will be collected by research team members (Prof. Bhuvaneswari Krishnamoorthy, Mr. Moslem Abdelghafar and Mr. Rick Air).
Data such as age, sex, race, body mass index, hospital admission, duration of the surgery, medications, consumption of alcohol, tobacco, blood pressure, heart rate, breathing rate and type of cardiac surgery. In addition, we will be collecting questionnaires (State trait-anxiety inventory, VR- experience) which you will be completing during your stay.

What will happen to me if I take part?

Patients who are about to have heart surgery at Wythenshawe Hospital will be split into two groups by chance: one group will get a Bluetooth music headset Figure 1, and the other will use virtual reality (VR) technology (Figure 2). The pretend treatment group will go through the usual process before surgery, which includes reading a booklet about the surgery, watching a video talk on the internet, and listening to music with a special Bluetooth music headset. The VR group will do the same things, but they'll also have two VR sessions: one right before surgery and another on the third day after surgery.

If someone in the VR group needs help breathing with a respiratory machine and not woken up after the operation on the third day, they won't be part of the study anymore, and we'll find new patients to take their place in both groups. We'll give questionnaires

to all the patients before and after surgery to ask them about how anxious and stressed they feel, and we'll also check their physical measurements. For the VR group, we'll also ask them about their VR experience.

Cortisol swabs from your mouth:

Additionally, we'll check if there's a link between the level of a stress-related substance called cortisol in their saliva and their answers on the questionnaires. Cortisol is a steroid hormone that is produced by your 2 adrenal glands, which sit on top of each kidney either side of your abdomen. When you are stressed, increased cortisol is released into your bloodstream. We'll take saliva samples from everyone before and after the Bluetooth music headset or VR, both before and after surgery, to see if there's a connection.

We will be collecting 4 cortisol swabs in total from inside your mouth towards your cheeks area. The saliva will collect gently with cotton swabs by the researcher. You will not feel any pain or discomfort. We will be storing this immediately into the sterile cylinder container and sent it to the hospital laboratory for examination to check your stress level. If there are any saliva samples left over after the examination which will be thrown away by the laboratory scientist as per hospital policy.

Figure 1: Bluetooth music headphone

Figure 2: VR headset

What are the other possible complications?

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.

What are the possible benefits of taking part?

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.

What happens if I change my mind?

You can withdraw anytime during the study period without giving a reason. Not taking part or withdrawing from the study will not have any impact on your clinical care or surgery. All the data which includes your personal details such as questionnaire and saliva samples will be removed. Please note that any data which has been collected anonymously will be used and it is not possible for us to remove anonymous data after you have withdrawn from the study.

Where will the results/information be published and how it will be used?

It is intended that the results of the study will be published in academic journals, presented at national and international conferences and published in medical journals so that we can explain our research results to the medical community. Your name will never appear in any report or publication arising from this study.

If you wish to receive a copy of the study results you will be asked to supply your preferred contact details on the consent form.

Will my information be kept confidential?

Your information will be kept confidential and secured at all times, in line with the new Data Protection Act (2018). All the information collected for this study from you will be stored in a pseudo-anonymised under lock and key within MFT premises by research team members. Only anonymised data will be shared with the statistician for data analysis. Data will be archived for ten years at the end of the study.

Please note: There are certain circumstances where confidentiality has its limits. The researcher has a professional obligation to act if a disclosure is made that suggests, either directly or indirectly, harm to the participants or to others, or criminal activity or bad practice. In this eventuality, only the appropriate people/professional bodies would be privy to that information. The research will discuss this with you if there is a need.

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the lead researchers who will do their best to answer your questions (Prof. Bhuvaneswari Bibleraaj on b.bibleraaj@salford.ac.uk). If you remain unhappy and wish to complain formally, you can do this by contacting the University of Salford ethics team on ethics@salford.ac.uk or University of Salford Ethics Chair Dr. Katy Szczepura k.szczepura@salford.ac.uk.

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have legal grounds for legal action against for compensation at the Trust, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

1. **Who has reviewed this study?**

This study is being sponsored and funded by University of Salford Pump Priming Fund 2023. There is a contract signed by the university of Salford and Manchester foundation Trust to allow us to conduct this study at Wythenshawe hospital. All research in the NHS is approved by the Health Research Authority (HRA) and reviewed by an independent group of people called a Research Ethics Committee (REC). The Research Ethics Committee is made up of experts, non-experts and members of the general public. Together they review research applications to ensure your safety, rights, wellbeing and dignity are protected at all times.
The study has been reviewed and given favourable opinion by Greater Manchester East Ethics committee on 02/01/2024.

2. How will we use information about you?

We will need to use information from you, your medical records and your GP for this research project.
This information will include the following:

- Your NHS number.
- Age
- Gender
- Medical History including test results.

People who will access your details are:

- 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 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.

3. What are the 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.
- We will not be using any data for future research from this study.

4. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- At https://research.cmft.nhs.uk/getting-involved/gdpr-and-research
- by asking one of the research team members from your hospital.
- by sending an email to b.bibleraaj@salford.ac.uk

Many thanks for reading the participant information sheet.

RSVR research team

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