**REC Ref: 24/WS/0158** **IRAS ID: 346340**

**Participant Information Sheet (PIS)**

**Study Title:** Patients Experience and Acceptability of Using a Virtual Reality Headset as an adjunct to rehabilitation following major trauma: A Qualitative Study

**Chief Investigator:** Martin Cartwright

Principal Investigator: Beth Kenny

**Research Sponsor: City, St George's University of London**

Where "we" is used throughout this sheet, it refers to the Research sponsor.

**Invitation to participate in the above study:**

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following carefully and discuss it with others if you wish. **We will go through the information sheet with you and answer any questions you have.** We'd suggest this should take about 5-10 minutes. This information sheet is yours to keep.

**What is the purpose of the study?**

The purpose of this study is to gain an understanding of patients experience of using a virtual reality (VR) headset intervention alongside their rehabilitation on the ward whilst recovering from major trauma.

**Why have I been invited?**

You have been invited because you used VR whilst recovering from major trauma, whilst an inpatient at St George's hospital.

**Do I have to take part?**

No. Taking part in this research is entirely voluntary. It is up to you to decide whether you wish to take part. If you decide to take part, you will be asked to sign a consent form. You can withdraw from the study at any time and

without giving a reason. A decision not to take part in the study or to withdraw from the study will not affect the standard of care you receive.

**What will happen to me if I take part?**

You will complete a consent form to confirm you are voluntarily agreeing to participate in the study. We will ask you to complete a short form which provides us with more information about yourself and your injuries. We will arrange a time at your convenience to conduct a single interview with the researcher Beth Kenny. This 30-minute interview can be carried out remotely via Microsoft Teams or face-to-face at St George's hospital, according to your preference. The interviews will be recorded via a password protected tape recorder if conducted face-to-face or via a hospital secured Microsoft teams account if carried out remotely to allow for the researcher to transcribe or analyse the interview afterwards. The recordings will be uploaded onto a password protected trust computer only accessible to the research team. Each recording will be transcribed into an anonymised written form. At this point the original recording will be deleted.

**How will we use information about you?**

We will need to use some information from your medical notes to:

(1.) confirm that you are eligible for this study

(2.) contact you about the study

(3.) enable us to describe the participants when we write-up the research report (if you choose to take part in the study)

To enable us to give a more detailed description of the participants, we will also ask you to complete a brief survey that asks about your ethnicity, working status and education level.

| Information from medical records: | Information from the brief survey: |
|---|---|
| • Name<br>• Hospital number<br>• Contact details<br>• The area you live<br>• Sex and gender<br>• Age<br>• How you were injured and what you injured | • Ethnicity<br>• Working status<br>• Education level |

You can choose not to complete part or all the survey and you can ask that specific information from your medical records (e.g. age) is not used in our research reports. However, having a detailed description of the participants helps us interpret the findings of the study.

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. Everyone involved in this study will keep your data safe and secure (see data privacy statement page 6).

**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, we will ask you if we can keep information about you that we already have. However, you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study.

**Will my taking part in the study be kept confidential?**

Yes, we will follow ethical and legal guidelines to ensure that your name will never be revealed and all the personal data we collect from your medical records and from the interview (e.g. age, how you were injured, educational level) will remain strictly private.

The findings from the study will be presented at meetings and conferences and published in scientific journals. To do this we will use quotes (i.e. short extracts) from the interviews, but we will never reveal the names of the people who took part in the study. Any quotes that we do use will be 'de-identified'. This means that all names (not just yours but also the names of your family members, healthcare professionals, hospitals etc.) will be removed. We will also remove any other information that might be used to identify you, the healthcare professionals who treated you or the hospital where you were treated.

We will follow strict data protection procedures to ensure that any information we collect about you is securely stored and cannot be accessed by anyone outside the research team. When the study is completed, all paper and digital records that contain personal data about you (e.g. your name, age, email address etc.) will be destroyed.

**What do I have to do?**

- If you agreeable to take part in the study, you will participate in a 30-minute interview with the researcher, Beth Kenny.
- The interview will focus on your use of the virtual reality headset during your rehabilitation while you were you're an inpatient at St George's Hospital
- You will complete a consent form and you will be asked to provide some socio-demographic details either face-to-face or verbally over phone with a member of the research team.
- You will arrange a time with the researcher to complete a single interview, either face-to-face when you attend an outpatient appointment at St George's hospital or over Microsoft Teams if chose to complete it remotely.

**What are the possible disadvantages and risks of taking part?**

The are minimal risks to your participation. However, we will be asking you to reflect on your inpatient admission following your accident/ injury. Although the focus will be on the virtual reality headsets, talking about your rehabilitation can be challenging for some patients following a trauma.

You will be able to pause or postpone the interview at any time. You will be interviewed by an experienced clinician with expertise in major trauma injury and they can support you with signposting to psychological support services or other after trauma support services that may be helpful if this is necessary.

**What are the possible benefits of taking part?**

This research will help to understand whether the use of VR in an inpatient setting is helpful for patients following major trauma. The findings may be used to inform our clinical practice and research looking at the use of VR following major trauma.

**What happens when the research study stops?**

The information collected in the study will be analysed and formally written-up. This information will be shared with participants and the findings will be made available to health care professionals through meetings,

conferences and scientific publications and to the wider public through social media. Participants in the research will be offered a summary of the findings.

The de-identified data collected about you will be kept for 10 years, a locked secure room following formal archiving process. Within this time it may be used for future studies. However, you can opt out of this in the consent process if you wish.

**What if there is a problem?**

Any complaint about the way you have been dealt with or any possible harm you might suffer will be addressed (See below for further details).

**What will happen if I don't want to carry on with this study?**

If you decide you do not wish to participant in the study before, during or after the interview, you can withdraw from the study and remove any interview data that has been collected. This will not impact your care in anyway. You simply will inform the research team that you no longer wish to take part in the study, and we will formally withdraw you. We may ask you why you no longer want to participate but you do not have to provide a reason if you do not want to.

**What if there is a problem?**

If you have any problems with how the study is conducted, we want you to feel comfortable to inform the research team so the problem can be addressed in the first instance. However, should you not feel comfortable doing this we would invite you to make a formal complaint utilising the Patient Advise and liaison services (PALS).

**Principal Investigator:** Beth Kenny

**Research Team Contact details:** T&OResearch@stgeorges.nhs.uk

**Phone number:** 02087250985

**PALS:** 02087252453

**PALS Email**: pals@stgeorges.nhs.uk

If you are still not satisfied with the response, you may contact the Joint Research and Enterprise Services team at St George's.

**Contact:** researchgovernance@sgul.ac.uk

**City, St St George's University of London**

has agreed that if you are harmed because of your participation in the study, you will be compensated, provided that, on the balance of probabilities, harm was caused as a direct result of the procedures you experienced during the study. These special compensation arrangements apply where harm is caused to you that would not have occurred if you were not in the trial. We would not be bound to pay compensation where: The harm resulted from a procedure outside the trial protocol and/or the protocol was not followed. These arrangements do not affect your right to pursue a claim through legal action.

**Who is organising and funding the research?**

The study is organised by City, St George's University of London. The research is being self-funded by the Trauma and Orthopaedic Research team and the clinical team who will conduct the research. The Research is being completed as part of a dissertation in Clinical Research at City, StGeorge's University of London. No identifiable information will be shared with City, St George's University of London but academic support on how the data is analysed and written up will be provided for quality assurance.

**Data Privacy statement**

City, St George's University of London (CSGUL) is the sponsor and the data controller of this study based in the United Kingdom. This means that we are responsible for looking after your information and using it properly. The legal basis under which your data will be processed is SGHFT public task.

You can find out more about how we use your information for research at City, St George's University of London the below link:

CSGUL Privacy link:

20180717-PrivacyNoticeTemplate_ResearchStudies

For general information on how the NHS uses research data please 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/

**Who has reviewed the study?**

*All research in the NHS is looked at by independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favorable opinion by West of Scotland Research Ethics Service.*

**For Further Information Please contact:**

Bethany.kenny@stgeorges.nhs.uk

*0208072503225*

Bleep through Switch board: 6774