FULL/LONG TITLE OF THE STUDY	Patients Experience and Acceptability of Using a Virtual Reality Headset as an adjunct to rehabilitation following major trauma: An Interview Study
SHORT STUDY TITLE / ACRONYM The short title should be: • Sufficiently detailed to make clear to participants what the research is about in simple English • If acronyms are used the full title should explain them. The proposed acronym should not drive the long title	VR in Major Trauma Rehab: A qualitative Study
PROTOCOL VERSION NUMBER AND DATE Version control: • All draft versions should be numbered 0.1, 0.2 etc. • The final version for submission should be numbered 1.0 • The changes made relative to the previous protocol version should be listed after submission	**2.1**
IRAS Number:	**346340**
JRES Reference Number	**2024.0197**
Funder Reference Number:	**n/a**
This protocol has regard for the HRA guidance and order of content	

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date: 08/10/2024
06/02/2025

Name (please print):

Kavetta Arulanantham

Position: Research Governance and Facilitation Officer

Chief Investigator:

Signature:

Date: 20-01-2025

Name: (please print):

Dr Martin Cartwright

Chief Investigator

Senior Lecturer in Health Services Research

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Funder(s)	Non-funded Research is being conducted as part of a dissertation for an MRes in Clinical Research at London City university
Key Protocol Contributors	Bethany Kenny (Bethany.kenny@stgeorges.nhs.uk) Martin Cartwright martin.cartwright.1@city.ac.uk Kristen.barnicot@city.ac.uk
Committees	Not applicable

STUDY SUMMARY	
Study Title	Patients' Experience and Acceptability of Using a Virtual Reality Headset as an adjunct to rehabilitation following major trauma: A Interview Study
Internal ref. no. (or short title)	VR in Major Trauma Rehab: A qualitative Study
Study Design	Qualitative
Study Participants	Major Trauma patients from St George's hospital
Planned Size of Sample (if applicable)	10- 15
Follow up duration (if applicable)	Not Applicable
Planned Study Period	12 months
Study End	The study will end when the 10-15 participants data has been collected and analysed and the formal report has been written up. This is anticipated to in September 2025.

Research Question/Aim(s)	Patients Experience and Acceptability of Using a Virtual Reality Headset as an adjunct to rehabilitation following major trauma: An Interview Study The aim of this study is to explore the acceptability and usability of an active VR headset intervention as an adjunct to rehabilitation
FUNDING AND SUPPORT	
FUNDER(S)	No funding

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

This research is being carried out as part of a Master's in Research (MRes) which is being completed at City, University of London. The steering group member are the supervising the project.

Trial Steering Group	
Chair	Bethany Kenny, St George's University Hospital NHS foundation Trust Bethany.kenny@stgeorges.nhs.uk
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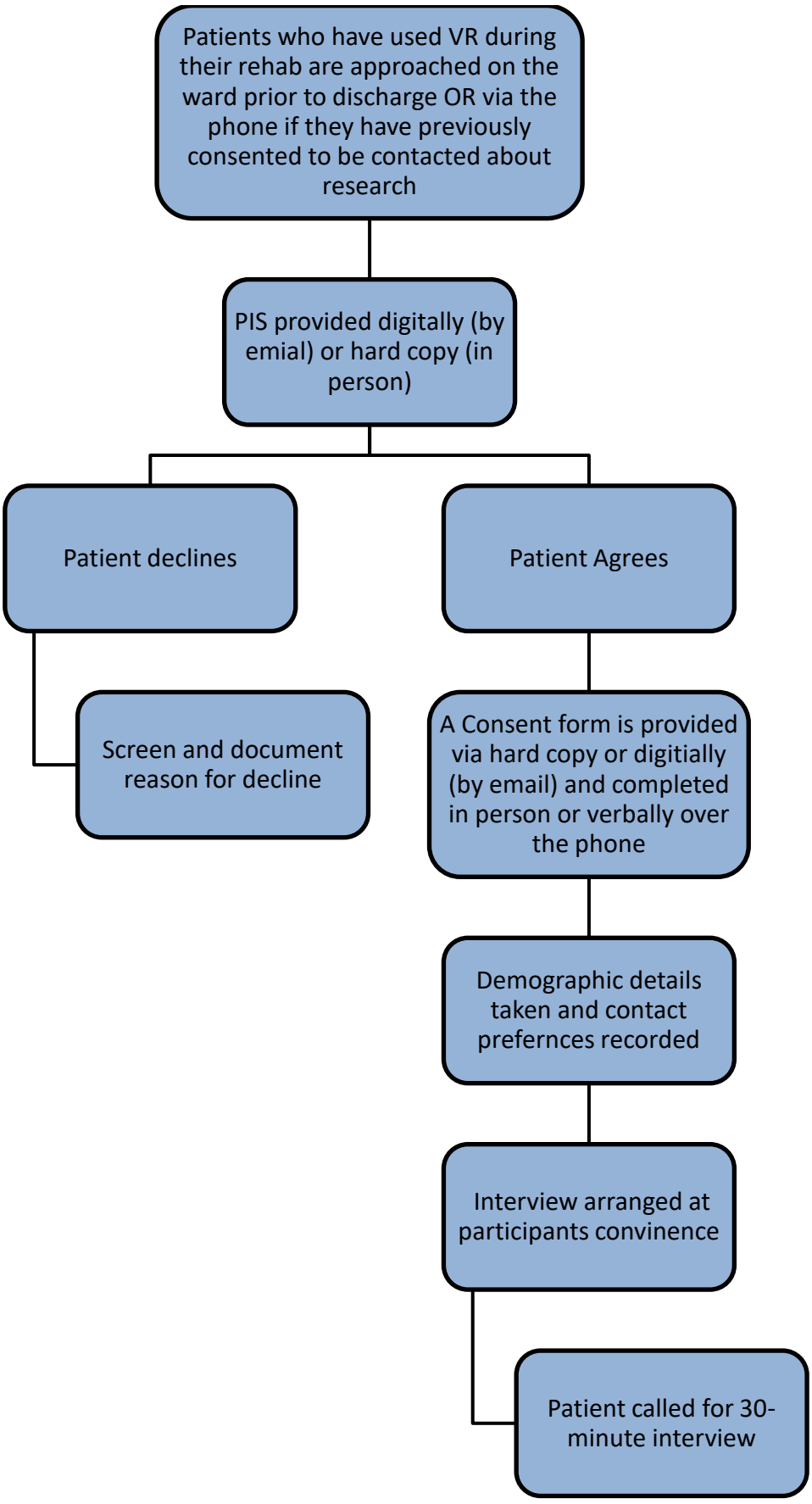
STUDY SCHEMATIC



ABBREVIATIONS	
AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
JRES	(St Georges) Joint Research and Enterprise Services
NHS	National Health Service
NIHR	National Institute for Health Research
PI	Principal Investigator
PIS	Patient Information Sheet
REC	Research Ethics Committee
SAE	Serious Adverse Event
SGUL	St Georges, University of London
SGHFT	St Georges, University Hospitals NHS Foundation Trust
VR	Virtual Reality

STUDY PROTOCOL

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

1 BACKGROUND

There are approximately 22,000 cases of major Trauma in the UK every year (Fisher, A. *et al.,* 2010) and with the addition of the London major trauma centres it has been estimated there is a 19% increase in the odds of survival following major trauma (Moran *et al.,* 2018). (NHS England, 2018) reported this as an additional 1600 patients being saved between 2012-2017.

Whilst more trauma patients are predicted to survive, research has shown there can be a reduction in quality of life after trauma (Vardon-Bounes *et al.,* 2021; Rosenbloom *et al.,* 2013). In a 5-year prospective follow-up study, the final analysis of 55 patients found 17% of patient did not return to work and 36.4% patients were acknowledged as having a disability (Vardon-Bounes *et al.,* 2021). Additionally, in a systematic review of persistent pain and psychological outcomes following musculoskeletal trauma, 28-93% of people reported lasting pain, within a three month to seven-year period post injury (Rosenbloom *et al.,* 2013). This demonstrates a need to find treatments that could help improve pain and recovery in this population.

Promoting early mobilisation and rehabilitation following traumatic injury is recommended, with benefits including maintenance of strength, range of movement, promotion of bowel movements, prevention of deep vein thrombosis, prevention of pressure sores and improved cardio-respiratory function (Guideline NG211, 2022; You, Leighton and Schneider, 2020). However, it should be acknowledged that achieving these recommendations whilst experiencing acute pain can be challenging in this patient group. In a cohort study looking at pain intensity post-surgery, Trauma and orthopaedic patients were amongst those reporting the most significant acute post-surgical pain intensity whilst moving compared with other surgical patients, who had under gone procedure such as major abdominal surgery (Gerbershagen *et al.,* 2013).

Given early mobilisation is recommended in this population, strategies that encourage mobilisation whilst positively influencing patients pain experience might be a useful approach.

A Virtual reality (VR) headset is relatively new technology being explored in many aspects of healthcare, including anatomical and physiology education, patient rehabilitation, public health training, medical training (e.g. surgical skills), viewing medical imagery and children's health (Helou *et al.,* 2023). Software applications have been specifically developed for use in healthcare for the purposes of physical and mental rehabilitation, however further research is required to understand its usefulness and usability particularly in the acute inpatient setting, where research is sparse (Helou *et al.,* 2023). VR headsets are advantageous

compared to other VR devices that have been explored in an inpatient setting as they are more portable and can be wirelessly linked to personal computers (PCs), smartphones, or tablets (Helou *et al.,* 2023).

Currently, a VR headset is being used as an adjunct to inpatients rehabilitation at a London Major Trauma Centre (Fisher, S., Tebbutt and Kenny, 2024). There are very few studies looking at the effectiveness of VR headsets following Major Trauma, and none conducted in the UK health system. One within-person randomised crossover trial, conducted on 60 patients in a single centre in the United States, showed VR to be safe and found it to have a modest tangible effect on pain (Morris *et al.,* 2023). An American case study using a single major trauma inpatient, compared doing range of movement exercises versus standard range of movement exercises using no adjuncts (Hoffman *et al.,* 2009). They randomly allocated the order in which the patient was exposed to the intervention and found the VR decreased pain, time spent thinking about pain and increased range of movement (Hoffman *et al.,* 2009). Whilst these studies are promising for the benefits of VR in major trauma patients, they have small sample sizes and are not specific to an NHS major trauma health population.

While evidence of effectiveness is limited, evidence of patients' experience and perceived acceptability of VR headsets is absent, with no qualitative studies examining these outcomes in relation to VR headsets in major trauma patients. This lack of evidence undermines efforts to develop rehabilitation strategies using this technology. Healthcare interventions perceived as being more acceptable by recipients (e.g. patients) and deliverers (e.g. healthcare professionals) are associated positive outcomes including greater uptake and adherence, improved effectiveness and cost-effectiveness and facilitation of implementation, sustainability and scalability (Sekhon, Cartwright and Francis, 2017; Perski and Short, 2021; Proctor *et al.,* 2011). In recognition of these benefits, the latest revision of the MRC's framework for complex interventions recommends assessing acceptability at multiple stages of development and evaluation(Skivington *et al.,* 2021).

The aim of this study is to interview patient who have used a VR headset as adjunct to their major trauma rehabilitation to gain an understanding of their experience and whether they deem it an acceptable treatment adjunct.

2 RATIONALE

According to the National institute of clinical excellence guidelines, rehabilitation should start as soon as possible following traumatic injury (Guideline NG211, 2022). However, many trauma patients face barriers to engaging in rehabilitation including, anxiety, depression, post-traumatic stress disorder, pain, pain catastrophising and fear of movement (Gabbe *et al.,* 2012; Archer *et al.,* 2012). Ways to address these barriers and promote early engagement in rehabilitation, could not only help the patients but also expedite

hospital discharge with ensuing cost savings. Using VR headsets in this population has the potential to support these clinical goals. However, given the physical and psychological complexities that major trauma patients can experience, it is important to gain an understanding of patients' perspectives about whether they think VR is an acceptable tool as part of their rehabilitation.

VR-based exercise therapy has been shown to improve pain and functional ability in different health conditions, such as chronic lower back pain, internal medicine, oncology, fibromyalgia, musculoskeletal shoulder conditions and knee osteoarthritis (Asadzadeh *et al.,* 2021). However, currently there is minimal research on the use of VR headsets specifically to support rehabilitation in the any acute inpatient hospital setting (Mosadeghi *et al.,* 2016; Kolbe *et al.,* 2021). Most inpatient VR headset interventions focus on relaxation therapy which does not necessarily promote early movement (Patterson *et al.,* 2010; Austin and Siddall, 2021; He *et al.,* 2022). As VR technology is becoming more sophisticated and accessible to health services more companies are approaching the NHS to invest in VR headsets for patients. Therefore, the NHS needs to assess the potential costs and benefits to patients and services and explore implementation challenges in different patient populations and settings (Helou *et al.,* 2023).

In our previous early scoping work at St George's hospital, a VR headset (Sync VR Fit) intervention was piloted with major trauma patients as an adjunct to their rehabilitation (N=18) (Fisher, S., Tebbutt and Kenny, 2024). This work reported that 72% found it 'extremely motivating' and 83% would 'definitely recommend' VR use as an adjunct to rehabilitation. However, this feedback was from a small sample of patients, relied on unvalidated questionnaires and was only able to provide only a limited assessment of patients' views.

The updated MRC Framework for developing and evaluating complex interventions (Skivington *et al.,* 2021) recommends assessing the acceptability of the intervention in the feasibility phase (and continually throughout the development and evaluation process) to inform refinement of the intervention and guide the decision to progress. For this purpose, phenomenological qualitative studies are required.

To address this evidence gap relating to patient experience and acceptability, the current study will conduct theoretically informed semi-structure interviews with major trauma patients to explore their experience of using VRHs and assess acceptability.

3 THEORETICAL FRAMEWORKS

This qualitative study will utilise a Phenomenological methodology with thematic analysis. A phenomenological study considers the lived experiences of a phenomenon for several individuals (Creswell and Poth, 2016). Qualitive research attempts to uncover a deeper human experience through open

questioning to produce rich descriptive data (Renjith *et al.,* 2021). Renjith et al. (2021) highlights the benefits this data can have for designing interventions and rationalising there use in healthcare. This approach seems particularly appropriate for this patient population who are often experiencing complex psychological emotions and physical challenges following their injuries (Gabbe *et al.,* 2012).

Thematic analysis is systematic way of offering insight into a data set by identifying patterns or themes, it aims to make sense of a collection of shared experiences (Braun and Clarke, 2012). Braun and Clarke (2012) offer a six-stage approach to analysing a data set which will be used in this qualitative study, this includes:

1. Familiarisation- Becoming acquainted with the data set
2. Generating initial codes- a label for a feature of data that is potentially relevant to the research question
3. Searching for themes- codes transition to themes based on patterned response
4. Reviewing potential themes- developing themes are reviewed in relation he coded data and whole data set, themes may be brough together or broader themes divided into more specific themes
5. Defining and naming the theme- Clearly state the specifics about each thing and what makes them unique
6. Producing the report- provide a compelling narrative about your data based on your analysis

To investigate patient's experience, the study will utilise an inductive and exploratory approach to generate novel insights from patients who have used VR to establish how they feel it might have helped them. An inductive, exploratory approaches seek to investigate areas of research that have been minimally examined it allows for a systematic approach that is flexible enough to accommodate changes in the research focus due to unexpected findings (Rendle *et al.,* 2019).

4 RESEARCH AIM AND OBJECTIVES

Aims: To explore patients' experience and acceptability of using a physically active VR Headset intervention as an adjunct to their rehabilitation following major trauma via semi-structure interview.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Study design

Single centre cross-sectional interview study.

Data collection

Data will be collected by using a semi-structured topic guide. Questions relating to the acceptability of the VR headsets are informed by the Theoretical Framework of Acceptability (TFA)(Sekhon, Cartwright and Francis, 2017).

Recruited patients will be contacted over the phone by the Principal investigator to arrange an interview which will be conducted over video call, via Microsoft teams in a private location or face-to-face in a private room when patients attend hospital for follow-up appointments. We will aim to conduct interviews within 1-month of consenting to participate in the study. Face-to-face Interviews will be recorded via a password protected voice recorder and uploaded securely onto a password protected digital site file on a trust computer. For interview conducted by Microsoft teams, the interview will be audio recorded via Microsoft teams and downloaded securely to password protected site file. They will be transcribed by the chief investigator who will remove any identifiable details. The transcribed material will be held on password protected site file on a St George's Trust computer and the audio recording will be deleted immediately after this transcription process.

Data Analysis

Interview transcripts will be analysed using the Thematic Analysis approach described by Braun and Clarke (2006). Interviews will be transcribed with the support of Microsoft transcription software. Transcriptions will be uploaded to NVIVO for data analysis. Here transcriptions will be coded, codes will be developed into themes, themes will be reviewed and further synthesised once all the data has been captured. Following this the themes will be clearly defined which will guide the production of the final report (Braun and Clarke, 2006).

To investigate the acceptability of VR headsets from the patients' perspective, the TFA will be used (Sekhon, Cartwright and Francis, 2017). This framework posits seven constructs that reflect the underlying key dimensions of acceptability of healthcare intervention (Affective attitude, Burden, intervention coherence, ethicality, opportunity costs, perceived effectiveness and self-efficacy) Sekhon, Cartwright and Francis, 2017)

These constructs inform the interview topic guide (see Appendix 7). To analyse data relating to acceptability a 2-stage process with be completed. In stage 1, text from the interview transcripts will be deductively coded into the seven TFA constructs to provide the core corpus of data for analysis. In stage 2, text within each construct will be inductively analysed to construct themes that reflect the content and meaning of the data.

Rigour

In TA, Braun and Clarke (2019) explain the importance of reflexivity in the study design. This requires a researcher to acknowledge their assumptions and positionings and the impact this has on the data analysis (Braun and Clarke, 2023; Braun and Clarke, 2021).

In this instance the researcher is a clinician already utilising VR in a Major Trauma setting therefore they may have pre-conceived notions of its benefits that they will seek out during coding and theme development. By taking a conscious inductive and reflective approach in data analysis the researcher is trying to minimise the risk of this. The researcher will approach the data with an open mind and consider whether there could be alternative explanations for themes identified. To further reduce the risk of bias in this study, the researcher will utilise the support of academics who do not have experience of using VR in a major Trauma setting to review themes generated from the data and challenge conclusions drawn from this.

To ensure rigour of analysis, we will use methods to enhance Lincoln & Guba's (1985) widely applied concepts of credibility, transferability, dependability and confirmability approach. We will reflect on our ability to meet these criteria in the final report (Lincoln, 1985).

6 STUDY SETTING

This study is being conducted with Major Trauma patients from St George's Hospital.

Participants who consented to take part will be offered to have the interview conducted face to face in line with an upcoming outpatient appointment for their convenience or they will be offered to conduct the interview via the video teleconference (Microsoft Teams).

Face to face interviews will be carried out in private clinical room at St George's hospital. Where interviews are conducted over the phone, the researcher conducting the interview will be in a private space and ensure the patient being interviewed feels they suitable location to conduct the interview. All interviews will be recorded.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Patients at St George's hospital who underwent treatment for Major trauma injuries who had exposure to using the VR Headsets as an adjunct to their rehabilitation will be eligible for the study

7.1.1 Inclusion criteria

- Participants aged 18 and over

- Who sustained Major Trauma injuries as per the TARN inclusion criteria who used physically active Virtual reality headset as an adjunct to their rehabilitation on the major trauma ward

7.1.2 Exclusion criteria

- Unable to speak fluent English
- Those who lack capacity to engage in the formal consent process or where the treating clinicians (e.g. doctor or occupational therapist) feels that there is cognitive impairment present that would impact the patient from engaging in an in-depth semi-structured interview
- A prisoner or vulnerable adult who will have difficulties organising and attending a face-to-face or over the phone interview safely and conveniently

7.2 Sampling

The study will recruit 10-15 participants using a convenience sampling method.

7.2.1 Size of sample

The study will aim to recruit 10-15 participants. This sample size is similar to other interview studies looking at VR health interventions, with samples of 12 and 14 participants (Deighan *et al.,* 2024; Healy *et al.,* 2023). The rationale for this sample size also considers the researchers time availability to gather data.

7.2.2 Sampling technique

Convenience sampling is also being used. Renjith et al. (2021) state how this process involves collecting data from subjects who are accessible, in geographical proximity and with low-cost implications. Given an opportunity may be missed to approach a patient that is eligible, and participants might be approached who are due to come in for appointment at a time convenient to them and the researcher, this study will also be using a convenience sampling method.

7.3 Recruitment

7.3.1 Participant identification

In the Trauma and Orthopaedic team at St George's we have split clinical and research roles that work across the T&O department as treating therapists and within research. These staff members have training in Good Clinical Practice (GCP) and will appear on the study delegation log. They will be responsible for patient identification and recruitment.

There are two main methods for identifying patients:

1. Major trauma Physiotherapists and occupational therapists who are using the Virtual Reality (VR) headset with major trauma inpatients will highlight the patients to the research team. The Research physiotherapists that work within the Trauma and Orthopaedic team will formally screen the patients for eligibility. The chief investigator and delegated research physiotherapists will approach the patients on the ward to invite them to participate in the study.
2. The Major trauma therapy team is due to start another trust approved quality improvement project in September 2024 on the use of the VR headsets in Major Trauma. The patients who have used the VR headset as part of their inpatient rehabilitation are being asked if they would mind being contacted, after discharge, by the T&O therapy team about future research or quality improvement projects relating to VR in Major Trauma. If they agree to this, it is being documented within their medical notes and being recorded as part of the quality improvement project. Therefore, there will also be a list of potentially eligible patients that could be approached by the research physiotherapists over the phone to invite them to participate. Anyone approached and consented via this method will undergo interview within 12-months or having used the headset, to ensure recent exposure to the device and more accurate reflections on their experience.

The research physiotherapists responsible for approaching patients are experienced in major trauma rehabilitation and can assess patients' mental capacity and ability to provide consent. If the research physiotherapists are having doubts regarding English language fluency and, or cognitive impairment preventing them from participating in an interview, they will utilise the treating clinicians to reach this decision. If a patient is identified as eligible, the research physiotherapists will approach the patients verbally to discuss the study and confirm eligibility with the patient. If the patient is interested in participation, they will be provided with a patient information sheet (PIS) and given then opportunity to ask questions. The Research Physiotherapists will allow the patients 24 hours and more time if necessary to review in the information and further opportunity will be given to ask questions. If the patient is agreeable to the study they will initiate a formal consent process.

7.3.2 Consent

Both in-person and verbal consent methods via the phone will be made available to the patient based on the patient's preference. The research team will ensure that the patient has read the Patient Information Sheet (PIS) (See Appendix 4) which details the nature of the research, the risks involved with participation and emphasises the right to withdraw at any time. The patient will be given time to ask any questions and have key points of PIS verbally re-iterated to them, this will be documented in the clinical notes.

In-person consent

For patients approached face-to-face they will be provided with a paper consent form. Consent will be taken either on the ward or during an outpatient appointment following their discharge. Participants will be asked to read the ICF and initial each box on the consent form (see appendix 5). They will sign and date the bottom of the form alongside the researcher taking consent. The Researcher will indicate on the consent form that consent was taken in person. A copy of the consent form will be uploaded to the participants clinical notes and the participant will be provided a copy. The original version of the ICF will be stored in a file separate to any identifiable information about the patient, this file will be kept in locked storage unit only accessible to the trauma and orthopaedic research team, the storage unit will be kept in a locked room.

Verbal consent

Consent will be completed over phone. The researcher will utilise the same paper version of the ICF and read out each point to the participant over the phone. Each box will be initialled with researchers' initials, they will write the patients name and the date consent was taken and then the researcher will put their own name, signature and date confirming they took consent. The box indicating a verbal consent process was used will be ticked. The patient must be sent a copy of the consent form electronically of via post according to the patient preference. This process will be documented in the clinical notes. An original copy of the consent form will be stored in the same way as face-to-face consent version.

7.3.3 Data collection tools

Sociodemographic data collection tool

A short demographic questionnaire will be taken with patient following consent prior to interview. This will capture information regarding age, mechanism of injuries, what the patient injured, length of hospital stay how many times they used the VR headset, ethnicity, working status, education status. Where possible this will be obtained from the medical notes, missing information will be confirmed with the patient. See **appendix 6** for sociodemographic data collection tool.

Semi-structured interview tool

An interview topic guide has been designed to guide the participants 30-minute interviews to ensure similar content coverage and style of questioning across participants.

This Semi-structured 30-minute interview will be conducted conversationally with one respondent at a time (Adams, 2015) . Predominantly open-ended questions will be asked however a blend of open and closed

questions will be used, accompanied by follow-up questions as appropriate, this process aligns with guidance given by Adams (2015) on conducting semi-structured interviews.

The development of the interview topic guide has been informed by clinically relevant existing research and theory. Questions about patients' experience based on topic guides used other interview study exploring patients' views of rehabilitation study after physical trauma (Connolly *et al.,* 2024) . Questions assessing the patients' perceived acceptability of the intervention were informed by the TFA and the TFA questionnaire(Sekhon, Cartwright and Francis, 2022) (See Appendix 7)**.**

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

The study is low risk but the main risks identified are as follows:

Risk 1. Topics covered in the interviews could provoke distressing thoughts or emotions

The study will not aim to elicit strong emotional responses; however, patients will be asked to reflect on a period of their recovery from traumatic injury which may understandably cause this.

Risk 1 Mitigation:

To mitigate the impact of potentially distressing topics, participants will be reminded at the start of every interview (and throughout, as required) that they can decline to discuss any topics that they are uncomfortable talking about and take a break at any time. Also, they will be advised that the interview can be stopped and resumed at another time, according to the participants need.

They will also be reminded that the study is optional and that they can withdraw from the study (and retract their interview data) at any time, without question or impact to their future healthcare. As an experienced physiotherapist and researcher, the researcher (BK) is able to recognise more severe stress reactions and in these circumstance participants will be signposted to appropriate psychological service or other post trauma services in the hospital, depending on the issues identified.

Risk 2. Confidentiality and data protection

Participants have a right to anonymity. They will consent to quotes from the interview being used in research reports, but their identity must be protected. The risk of unintentionally identifying participants can sometimes be greater when participants are recruited from a narrowly defined population (e.g. patients undergoing VR-enhanced rehabilitation in a Major Trauma Centre in London).

Risk 2 mitigation:

To mitigate the risk of unwittingly identifying participants, steps will be taken during each stage of the research process (data collection, data transfer, data storage and reporting):

- Copies of the patient consent forms being sent by email will comply with the trusts NHS encrypted email guidelines which allows secure emails to be sent to globally hosted email services.
- Copies of consent forms requested from the patient by post, will be sent in accordance with trusts NHS external posting systems and marked Private & Confidential.
- Interviews will be conducted in a private space.
- If an interview is conducted over video call, the researcher will ensure the patient is in a private space
- Interviews will be recorded onto an encrypted password protected digital device for transfer.
- Identifiable data (i.e. digital audio files of interviews) will be stored in an encrypted file on a password protected PC / laptop at the study site, only accessible by the lead researcher (BK).
- Interview data will be transcribed by [the lead researcher and the transcripts will be fully de-identified prior to analysis (i.e. all identifying information will be deleted, including but not limited to: names of patients, healthcare professionals, wards and hospitals; other patient and setting details; any information that could alone or in combination reveal the identity of participants). The original (potentially identifiable transcripts) will be securely deleted once de-identification is completed.
- Participants will be attributed a unique identifier which will be used in all reports, filenames and other study documentation. A file linking the unique identifiers to participants' identities will be stored in an encrypted file on a password protection PC / laptop, only accessible by the lead researcher (BK).
- Demographic and clinical descriptions of the sample will only be presented at the group level, not the individual level.
- All identifiable data (e.g. digital audio files; email correspondence) will be securely deleted on completion of the study (i.e. on completion of the MRes in Clinical Research programme).

The study will be conducted in compliance with GDPR requirements.

<u>COVID-19 Risk Assessment and Management Strategy</u>

All staff employed by SGUL and/or SGH NHS Foundation Trust are required to complete an ongoing COVID-19 risk assessment prior to undertaking any work on site, which includes research activity. This process is continuously monitored by the responsible line manager.

Participants (unaffected or affected) will not be recruited if they are deemed high risk or are in close contact with someone at risk. The Research Team will contact research participants ahead of scheduled study visits on-site to check for COVID-19 symptoms and the symptom check will be repeated when patients attend the hospital site for the study visit.

Participants will receive information regarding the extra precautions that will be taken in light of the COVID-19 pandemic in the PIS. This will detail steps that patients should take if they have concerns about exposure to COVID-19 through participating in the research, or believe that they are symptomatic or have been in close contact with another person believed to be symptomatic. The PIS will also have contact details for the Research Team for patients to get in touch if they have any concerns or queries about this.

All research personnel are expected to comply with the NHS Trust and University policies on COVID-19.

All patients attending the hospital site for research visits and/or routine clinical follow-up will be expected to abide by the NHS Trust and University policies on COVID-19 which include wearing suitable PPE (provided by the NHS Trust on arrival), adhering to the visitor policy on social distancing and following the one-way routing systems whilst on site.

The schedule of study assessments has been designed so that they align with the current routine clinical pathway for this patient population. Additionally, the schedule of study assessment has also been designed to allow for remote consent, recruitment and data collection which is thought to minimise the additional risk of exposure to COVID-19 to both research participants and staff through participation in this research.

Therefore, research participants and site staff are not perceived to be at any additional risk of exposure to COVID-19 through participation in this research study.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an appropriate REC for the study protocol, informed consent forms and other relevant documents e.g. semi-structure interview tool

For HRA- NHS REC reviewed research

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

- It is the Chief Investigator's responsibility to produce the annual reports and submit the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- The Chief Investigator will notify the REC of the end of the study within one year after the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

Amendments

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.3 Peer review

As this research project is being conducted as part of a dissertation for an MRes in Clinical Research the peer review process will be supported by dissertation supervisors at City, University of London where the MRes is being carried out.

8.4 Patient & Public Involvement

Patient and public involvement (P&PI) was conducted on 19th February 2024 with five patients and public members who had experience of treatment at St George's following Major Trauma. The purpose of the meeting was to gain a patient's perspective of how to best measure the potential benefits of VR in this patient group. The members of the group felt this was a valuable area of research.

The idea of a study investigating VR was pitched to the group by the lead researcher, the importance of research was explained and some of the formalities surrounding the research process. Our Major Trauma P&PI lead then took over the meeting and guided our patients through discussion points, including whether

the patients thought it was a useful topic to study, how they thought it would be best to understand patients' perspective on the topic (e.g. interviews, focus groups and questionnaires) and how data collection should be conducted (e.g. face-to-face, paper or digitally).We also discussed the potential risks to a study and emotions patient can face reliving parts of their recovery. Finally, we discussed the best ways to disseminate results of a potential study like this.

The members of the group felt this was a valuable area of research. They explained they would be open to different methods of data collection e.g. face-to-face in appointments, via phone or video calling. They felt there was more value in interview style of data collection as it would allow them to better convey their individual experiences compared to questionnaire data alone.

We also discussed whether a different qualitative methodology such as focus groups. Patients felt this may cause patients to withhold information or thoughts they had about the intervention in fear of becoming emotional or worried that the group wouldn't share the same views. They felt, whilst focus groups can help people have the courage to voice opinion and trigger thoughts it can also have the opposite effect and therefore one-to-one interviews would be better at gathering richer data. They also felt should emotional thoughts be triggered this would be better experienced in a one-to-one interview scenario.

They felt that social media and a summary of findings sent to individuals involved in research would be an appropriate method of dissemination of study findings.

8.5 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol.

All protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable and will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and patient confidentiality

All data will be handled in accordance with the Data Protection Act 2018 (UK implementation of the EU General Data Protection Regulation (GDPR)).

Any Case Report Forms (CRFs) will not bear the participant's name or other directly identifiable data. The participant's trial Identification Number (ID) only, will be used for identification. The Subject ID log can be

used to cross reference participant's identifiable information. Patients consent forms will be kept separately to any case report forms.

Participants have a right to anonymity. They will consent to quotes from the interview being used in research reports, but their identity must be protected. The risk of unintentionally identifying participants can sometimes be greater when participants are recruited from a narrowly defined population, mitigation of this risk is covered in the ethics section 8.1 of the protocol.

8.7 Indemnity

City St George's University of London sponsored research:

City, St George's University of London holds insurance to cover participants for injury caused by their participation in the clinical trial. Participants may be able to claim compensation if they can prove that City, St George's has been negligent. This includes negligence in the writing of the protocol, or selection of trial resources.

As the Trial is conducted in a hospital, the hospital has a duty of care to participants. City St George's University of London will not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees.

If a participant indicates that they wish to make a claim for compensation, this needs to be brought to the attention of City St George's University of London immediately.

Failure to alert City St George's University of London without delay and to comply with requests for information by the sponsor or any designated Agents may lead to a lack of insurance cover for the incident.

8.8 Access to the final study dataset

The Principal investigator and the Trauma and orthopaedic research associates will only have access to the full data set.

Named supervisors from City, St George's University will have access to de-identified versions of the data collected to support with appropriate data analysis.

The Joint Research Enterprise team at St George's Hospital will have access to de-identified data upon request.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Publication: “Any activity that discloses, outside of the circle of study investigators, any final or interim data or results of the Study, or any details of the Study methodology that have not been made public by the Sponsor including, for example, presentations at symposia, national or regional professional meetings, publications in journals, theses or dissertations.”

All scientific contributors to the Study have a responsibility to ensure that results of scientific interest arising from Study are appropriately published and disseminated. The Sponsor has a firm commitment to publish the results of the Study in a transparent and unbiased manner without consideration for commercial objectives.

To maximise the impact and scientific validity of the Study, data shall be consolidated over the duration of the Study, reviewed internally among all investigators and not be submitted for publication prematurely. Lead in any publications arising from the Study shall lie with the Sponsor in the first instance.

Before the official completion of the Study,

All publications during this period are subject to permission by the Sponsor.

Exempt from this requirement are student theses that can be submitted for confidential evaluation but are subject to embargo for a period not shorter than the anticipated remaining duration of the Study.

Up to 180 days after the official completion of the Study

During this period the Chief Investigator shall liaise with all investigators and strive to consolidate data and results and submit a manuscript for peer-review with a view to publication in a reputable academic journal or similar outlet as the Main Publication.

- The Chief Investigator shall be senior and corresponding author of the Main Publication.
- Insofar as compatible with the policies of the publication outlet and good academic practice, the other Investigators shall be listed in alphabetic order.
- Providers of analytical or technical services shall be acknowledged, but will only be listed as co-authors if their services were provided in a non-routine manner as part of a scientific collaboration.

Beyond 180 days after the official completion of the Study

After the Main Publication or after 180 days from Study end date any Investigator or group of investigators may prepare further publications. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at

least sixty (60) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor's reasonable comments shall be reflected. All publications related to the Study shall credit the Chief and Co-Investigators as co-authors where this would be in accordance with normal academic practice and shall acknowledge the Sponsor and the Funders.

9.2 Archiving Arrangements

Each site will be responsible for their onsite level study archiving. The Study essential TMF along with any central Study database will be archived in accordance with the sponsor SOP.

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11. APPENDICIES

11.1 Appendix 1 Schedule of procedures

	Schedule of Procedures			
Procedures		**Visits (insert visit numbers as appropriate)**		
	Screening	**Baseline**	**0-2 months**	**2-12months**
Patient Approached	**x**			
Informed consent	**x**			
Demographics		**x**		
Medical history		**x**		
Interviews			**x**	
Data analysis				**x**
Study write-up				**x**

11.2 Appendix 2

Amendment Log				
Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**

11.3 Appendix 3

Complete the form below. It will require review and sign-off by the Institute Director (SGUL) or the Care Group Lead (SGHFT).

Research Data Protection Impact Assessment (DPIA)

Data Protection Impact Assessments (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations under the Data Protection Act 2018 (DPA 18) and meet individuals' expectations of privacy.

A DPIA helps identify data privacy risks when planning new, or revising existing, projects and to identify actions to mitigate these risks. In the rare cases where risks cannot be mitigated at all it may be necessary to consult with the Information Commissioner's Office (ICO). Under data protection legislation it is a legal requirement to complete a DPIA in the following circumstances:

- where data processing is likely to result in a high risk of harm to individuals, e.g. new, invasive technology is proposed
- when large volumes of personal data are processed, e.g. use of behavioural profiles based on website usage
- when processing special category personal data on a large scale, e.g. healthcare data, genetic tests to assess and predict the disease/health risks
- where publicly accessible areas are monitored, e.g. CCTV or when filming public areas

Therefore a DPIA will be carried out for both internal and partnership projects which require the collection/processing of personal data in any format for the purpose of research.

The DPIA should be carried out towards the start of the project, in order to identify any associated information risks and mitigate in the early stages, before you start processing.

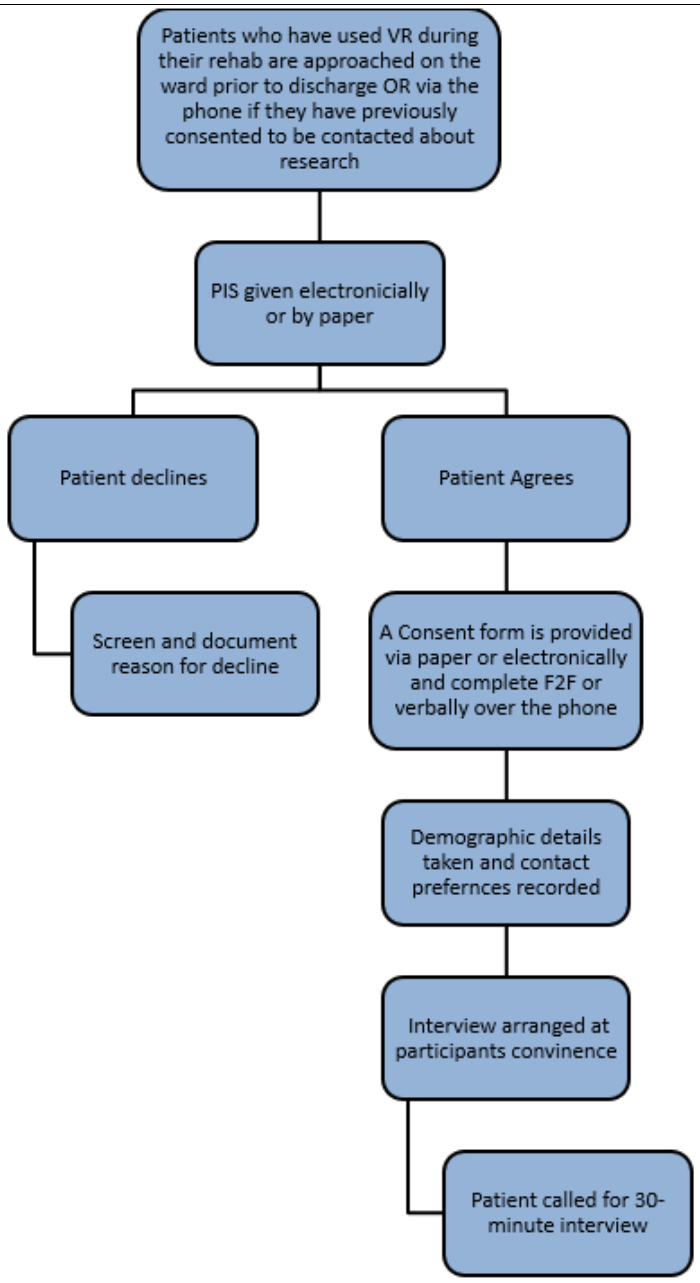
Study Title/Acronym:	VR in Major Trauma Rehab: A qualitative Study
JRES Reference Number:	
Chief Investigator Name:	Martin Cartwright
Chief Investigator Email Address:	Martin.Cartwright.1@city.ac.uk

PROJECT DETAILS
Project / process description: **- include / attach processing operations (include a flow diagram or another way of explaining data flows), the purpose and, where applicable, what St George's lawful basis is for the processing of the information.**
This is a single centre qualitative study which aims to conduct semi structured interviews with patients who have used VR as an adjunct their rehabilitation.

Eligible patients who have agreed to be contacted about participating in research relating to major trauma will be called and invited to participate in the study. Alternatively, they will be approached whilst still an inpatient or at an outpatient appoint at St Georges University Hospital . Patients who agree to take part will undergo a 30-minute interviews relating to their use of virtual reality (VR) as adjunct to their rehabilitation following Major Trauma will be conducted.

Socio-demographic information will be taken from their medical notes or clarified with the patient; this data will be captured on a case report form that is anonymised with their study ID number. Following this, interviews will take place either over the phone or face to face at St George's hospital in a secure location. The interview will be captured by a voice recorder and the uploaded securely to an electronic investigator site file kept at St George's Hospital. Paper consent forms and case report forms will be kept in a locked cabinet with a locked room, with the Trauma and Orthopaedic department.

Audio recordings of Interviews will be labelled with a unique study ID. This will be the same for the transcriptions of the interviews. Transriptions will not include the patients name if it was used in conversation during the interview.



What personal data do you intend to use, and why? (List all categories)

- A Participant tracker will be kept with patient's name, hospital number, contact number, study ID, and date the interview took place. This is a reference point for the researcher so source data can be found if required. This will be kept in a separate electronic folder and password protected so only the research team have access to it. This information will also be kept on EDGE (the local project management system)
- Original paper consent forms will be kept separately to the main investigator site file and archived at study close-down following St George's university hospital study close-down procedures. A version will be uploaded to their electronic notes and a copy given to the patient.

- Socio-demographic data will be captured on a case report form however this form will be labelled with the study ID only. This will be kept in a separate folder to consent form and uploaded to an electronic site folder kept separately to the participant tracker.
- Interviews will be recorded, participants will be referred to by their preferred name, the interview will be introduced assigning the participant a study ID. The date the interviews takes place will be audibly stated for the recording. Other than the patients preferred name this will be the only identifiable piece of information stated on the recording.
- Interviews will be uploaded onto a secure electronic site file and kept separately to identifiable participant information.
- These recordings will be transcribed, the transcription will only be labelled with their study ID and participants name will be replaced with the study ID where this was used in conversation.

Will the personal data be identifiable, pseudonymised or anonymised (if a mix tick accordingly)		
Identifiable		
*Pseudonymised		
Anonymised	✓	The candidate will be given a anonymised ID number e.g. SG-VR-01. SG-VR-02 etc

Confirm that the key to this data is kept securely away from the used data with strict controlled access

List all organisations / agencies which will have access to the personal data collection used for this project / process

- Only delegated members of T&O Research team will have access to personal data pertaining to this study.
- Personal data will be made available to the study sponsors at St George's University Hospital NHS foundation trust or St Georges University of London only where this has been formerly requested for legitimate reason.
- As this study is being conducted as part of a dissertation at City, University of London (MRes in Clinical Research) transcriptions of the interview may be shared over email securely with City, University of London however this will be anonymised with the study ID only

Length of the study – include an assessment of the necessity and proportionality of the processing in relation to the purpose. Also include who, internally & externally, has been consulted in the preparation of this DPIA.

6-12 months

	Schedule of Procedures			
Procedures		Visits (insert visit numbers as appropriate)		
	Screening	Baseline	0-4 months	4-12months
Patient Approached	x			
Informed consent	x			
Demographics		x		
Medical history		x		
Interviews			x	
Data analysis				x
Study write-up				x

Consultations:

- T&O Therapy team and Lead of T&O Research department
- JRES- Frankie Temple-Brown / Deidre Callahan
- Supervisors at City, University of London Martin Cartwright and Rachel Grant

If external organisations / agencies are involved, is there a contract or information sharing agreement in place with suitable clauses for data protection and data incident reporting,? If not why not?

The study is being conducted as part of a dissertation at City, University of London. They are currently undergoing a merger with St Geroge's University of London. That said identifiable information is not going to be shared with City, university of London, only the study protocol, blank versions on case report forms and semi-structured interview tool. Interview transcription data may be shared for analytical support, but this will be anonymised therefore it is not necessary for an information sharing agreement.

RISK

Can you achieve your objectives using anonymised data? – see ICO Code of Practice on Anonymisation

Yes	✓		
No		Why not?	

What are the benefits to the individual of their personal data being used for this purpose?

Minimal benefits come to the individuals other than a sense of purpose for supporting research into an intervention that may help others in the future who experience major trauma. The individual should be reassured that personal data can be held anonymously and only the essential members of the research team would be able to personally identify the individual.

What are the organisational benefits of the individual's personal data being used for this purpose?

This research will help gain an understanding about a novel intervention (Virtual Reality) for use within a Major Population. This can only be done by gaining an individual's personal perspective on the intervention. Capturing socio-demographics of the participants is important as it will inform readers of the research about the type of individual being interviewed and whether their perspectives can applied to other similar health populations if the research is trying to being implemented within practice. The personal data being collected can be held anonymously and only essential individuals from the research team would be able to personally identify the participants.

What are potential negative impacts to the individual of their personal data being used for this purpose in the event of a Data Breach occurring?

Negative impacts are not foreseen; however, a participant may not be willing for the wider population to have insight into their personal views on the user of VR in Major Trauma. They also may be reflecting on emotional or challenging situations they experience and in the event of a data breach and this display of emotion being leaked to someone who might be able to identify them, could cause psychological distress.			
How will you avoid causing unwarranted or substantial damage/distress to the individual when using their personal data for this purpose?			
Anonymising data collecting and with identifiable data, keeping it separate to anonymised data stored. E.g. consent forms kept separate to case report forms and interview transcripts.			
Is the data already held by St George's?			
Yes			
No	✓	This is a prospective qualitative study, once the data is collected it will be held by St George's University Hospital	
Is it held by one of the partner organisations / agencies involved in this process/project?			
Yes			
No	✓	Which agency will be collecting the data	n/a
Have you told the individuals whose personal data you want to use for this purpose, how and why you intend to use their data?			
Yes			
No	✓	Not yet, this is a prospective study, this will be conveyed verbally and within their copy of the participant information sheet.	
If not, are you intending to tell them?			
Yes			
No	✓	Why not?	Because it s a prospective study and the patients have not yet been approached. We intend to tell the patient verbally when approaching them and it will also be detailed in the information sheet.
Do you already have the individual's consent to use their data for this purpose?			
Yes			
No	✓	Why not?	No because it is a prospective study. What we potentially have is their consent to be contact over the phone regarding participation in research pertaining to major trauma so when the study is running, we may call them to invite them to participate. Where we do not have their consent to contact over the phone regarding research will only approach them face to face on the wards or in follow-up appointments
If not, are you going to ask for their permission?			
Yes	✓	Yes, during the consenting process.	
No		Why not?	
Have individuals been given the opportunity to refuse us permission to use their data for this purpose?			
Yes	✓	This will be part of the consenting process and is made clear on the participant information sheet.	
No			
How will you make sure that the personal data you are using is kept accurate and up to date?			

Through use of the medical notes and clarifying socio-demographic information with participant where it is not clear in the medical notes. Will document interactions with participants in their medical notes.

What steps or controls are you taking to minimise risks to privacy?
Please tick those which apply and provide details of how each is ensured

- Risks to individual privacy are minimal
- Personal data is pseudonymised
- Encryption of data at rest, i.e. when stored
- Encryption used in transfers
- Information compliance training for staff has been completed - data protection, information security, FOI
- Adherence to privacy by design principles
- Special category personal data is not used
- Participant opt out at any stage of the research
- Personal data kept in the UK
- Research is not used to make decisions directly affecting individuals
- Short retention limits
- Restricted access controls
- Other (please specify)

- Personal data anonymised with a study ID
- Information compliance training for staff has been completed - data protection, information security, FOI
- Personal data kept in the UK
- Research is not used to make decisions directly affecting individuals
- Restricted access controls- only relevant members of the research team will be given access to the electronic and paper investigator site files.
- The Participant Tracker will be encrypted.

How long will you need to hold the personal data for after the study has completed?

The study will be retained for a minimum of 5 years. Data will be held in compliance with the JRES standard operating procedures for clinical trials Version 6.0.
Close-out and archiving of the study will take place as soon as possible after the study has been formerly closed. Destruction will not take place unless confirmed by the sponsor.

How will you make sure that you are holding data for the appropriate length of time and no longer?

Through following the formal archiving process as above.

How will the data be held /stored?

Following the JRES archiving process.

Will you be using any electronic and/or paper Case Report Forms (CRFs) to collect data? If so what are these and how will they be held securely and managed at the end of the project?

Yes.
Paper:

- Original ICF's will be stored separately to the investigator site file in a locked cabinet in a locked room.
- Sociodemographic CRFs will be stored in the ISF

Electronic Study Tracker

- Will be stored in a protected folder on St George's L Drive. The Excel document will be encrypted.

Will personal data be transferred/shared between the organisations involved in this project? If so how?

Written transcriptions of interviews may be shared with supervisors and the City, University of London, however these transcriptions will be anonymised. If they are shared this will be via secure email.

Will you be transferring personal data to a country or territory outside of the UK? *If yes, name countries and receiving parties.*		
Yes – within EEA		
Yes – outside of EEA		
No	✓	

How will you ensure that third parties will comply with data protection obligations?
I will not share identifiable data with third parties.

What measures are in place to ensure only appropriate and authorised access to and use of, personal data?
A site delegation log will be utilised. Locked storage facilities that only T&O Research team have access too. Electronic site files will have restricted access and documents will be password protected where necessary.

How will technical and organisational security be monitored/audited?
As per JRES St George's University policy.

Declaration

I confirm that the information recorded on this form is, to the best of my knowledge, an accurate and complete assessment of the potential privacy impacts of this study.

Name:

Signature:

Date:

Institute Director (SGUL) or Care Group Lead (SGHFT)

Name:

Signature:

Date:

JRES Reviewer

Name:

Signature:

Date:

APPENDIX 4

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: 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 • Hospital number • Contact details • The area you live	• Ethnicity • Working status • Education level

• Sex and gender • Age • How you were injured and what you injured	

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).

Chief 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

City St Georges, 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 Londonon 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

APPENDIX 5

REC Reference Number: IRAS ID: 346340

CONSENT FORM

Patient Identification Number for this trial: _____

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

Name of Researcher: _____

	Initial each box
I confirm that I have read and understand the information sheet dated _____ version_____ for the above study and have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
I understand that I will be able to withdraw my data up to 'the time of anonymised interview transcription'.	
I understand that relevant information from my medical notes and personal data collected during the study maybe extracted by responsible individuals from St George's University Hospitals NHS Foundation NHS Trust or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
I agree to the interview being audio or videorecorded.	
I agree to de-identified quotes from my interview being used in reports and presentations of the study findings.	
I agree to take part in the above study.	
I agree to my de-identified interview data being used for future research.	**Optional** **Yes**_____ **No**_____
I would like to be informed of the study's results	**Yes**_____ **No**_____

_____ _____ _____

Name of Patient **Date** **Signature**

Consent taken in person ☐ *Consent taken verbally over the phone* ☐

I am confirming that if consent is taken verbally, I will ensure a signed copy is sent to the participant.

_____ _____ _____

Name of person taking consent **Date** **Signature**

When completed: Original stored in- Investigator Site File*; Copy given to Participant; and Copy stored in their medical notes*

APPENDIX 6 Sociodemographic tool

SOCIO-DEMOGRAPHIC CASE REPORT FORM

1. **AGE: _____**
2. **Length of hospital stay _____**
3. **Mechanism of Injury**
   - **a.** Fall from height ☐
   - **b.** Fall from Standing ☐
   - **c.** Road Traffic accident ☐
   - **d.** Pedestrian vs Motor vehicle ☐
   - **e.** Bicycle or E-Bike/ E-Scooter ☐
   - **f.** Crush Injury ☐
   - **g.** Assault ☐
   - **h.** Self-Harm ☐
   - **i.** Other:_____

4. **Patient Injuries (Multi-tick Box)**
   - a. Traumatic Brain Injury ☐
   - b. Skull fracture (Cranial/Facial) ☐
   - c. Upper limb fractures ☐
   - d. Chest Wall injuries and Thoracic Injuries ☐
   - e. Vertebral Fractures ☐
   - f. Abdominal Injuries ☐
   - g. Pelvic Fractures ☐
   - h. Lower Limb fractures ☐
   - i. De-gloving injury ☐
   - j. If multiple injuries, what did you consider to be your most significant injury

     _____

5. **Employment Status:**

   Working full time ☐

   Working Part-time ☐

   On paid parental leave ☐

   Unemployed ☐

   Retired ☐

   Student ☐

   Looking after home or family ☐

   Unable to work due to long-term illness or disability ☐

Other ☐_____

6. **Highest level of education achieved:**

Apprenticeship ☐

AS, A-Level or equivalent ☐

Qualification at degree level or above ☐

NVQ or equivalent ☐

GCSE's or equivalent ☐

No Qualifications ☐

Other ☐_____

7. **Ethnicity:**

White

1. English / Welsh / Scottish / Northern Irish / British ☐
2. Irish ☐
3. Gypsy or Irish Traveller ☐
4. Any other White background, please describe ☐_____

Mixed / Multiple ethnic groups

1. White and Black Caribbean ☐
2. White and Black African ☐
3. White and Asian ☐
4. Any other Mixed / Multiple ethnic background, please describe ☐_____

Asian / Asian British

1. Indian ☐
2. Pakistani ☐
3. Bangladeshi ☐
4. Chinese ☐
5. Any other Asian background, please describe ☐_____

Black / African / Caribbean / Black British

1. African ☐
2. Caribbean ☐
3. Any other Black / African / Caribbean background, please describe ☐_____

Other ethnic group

1. Arab ☐
2. Any other ethnic group, please describe ☐ _____

APPENDIX 7 Indicative Interview Topic Guide.

Indicative interview topic guide (version 1.0)

Brief opening statement

Thank you for agreeing to participate in this interview today. The interview should last for around 20-30 minutes, and we will mainly focus on your views of the virtual reality headset that used as part of your rehabilitation. You are free to not answer questions if you don't want to, just ask me to move on. We can pause the interview at any point to take a break. Are you happy to continue?

Q.1) Could you begin by telling be briefly about why you were admitted to our trauma unit?

Prompt: What was the incident that led to your injury?

How did this impact you while you were in hospital?

Q.2) You were offered rehabilitation while you were in hospital. What did rehabilitation involve for you? [prompt for all rehab activities, not just VR]

Prompt: Who was involved?

What actions/ exercises?

How much? How often?

Q.3) I understand that / you mentioned that VR headsets were used in your rehabilitation. Can explain to me what they are and how you used them?

Prompt:

- Were you standing or sitting or walking or moving when using the headset?
- What was it like when you put the headset on?
- What could you see? How realistic were the images/ sounds?
- How did it feel to wear the headset?
- What were you asked to do when the headset was on?

Affective attitude

Q.4) Did you like using the VR headsets?

Prompts: What did you like about using the headsets? [get specifics, prompt for more]

Was there anything you did not like about using the headsets? [get specifics (e.g. discomfort, disorientation, prompt for more]

Burden

Q.5) Did you find it easy or difficult to use the headsets? * Try to get participant to distinguish between using the VR and any specific …

Prompts:

- [If easy] What made them easy to use? / why were they easy to use?
- [If easy] Was there anything about the headsets that made them difficult to use? [e.g. discomfort, disorientation]
- [If difficult] What made them difficult to use?
- [If difficult] Was there anything about the headsets that made them difficult to use?
- During your rehabilitation, how often (and for how long) would you want like wear the headset?

Self-efficacy

Q.6) How confident were you about using the VR headset?

Prompts: Did you feel able to use the headset without help?

Intervention coherence

Q.7) Did you understand why you were asked to use the headset?

Prompts:

- How was the headset supposed to help your rehabilitation?
- Was there any advantage to using the headset (compared to not using it)?
- Did it make sense to you to wear the headset to help your recovery? [why?]

Perceived effectiveness

Q.8) Do you think using the headsets helped your rehabilitation? [how? why?]

Prompts:

- Did the headsets help you to recover more quickly?
- Did the headsets help you to recover more completely?
- If you had not used the headsets do you think you would have recovered as well as you have?

Opportunity costs

Q.9) Did the time and effort that it takes to use the headset prevent you from doing other activities that are important to you?

Prompts:

- Did using the headsets stop you from resting, reading, talking to family/ friends?
- Did using the headsets stop you from engaging in other important rehabilitation activities?

Ethicality

Q.10) Do you think there are any ethical issues raised by the use of the headsets for patients like you?

Prompts:

- Did somebody explain the reason for using the headsets to you before you were invited to use them?
- Did you feel that you could have refused to use the headsets if you had wanted to? [Did you feel pressured into using them?]
- Did you have any concerns about safety risks or side-effects of using the headsets?
- Did the headset make you feel vulnerable?
- Do you think the headsets would be appropriate for all patients? [Would any patients not be able to use them?]
- Are you concerned about the headsets collecting personal data about you?
- Did you feel embarrassed wearing the headset? [are they childish?]

Q.11) Overall, would you that using the headsets was an acceptable part of the rehabilitation process or not? [Prompt for elaboration / explanation]

That's all my questions for you, but before we finish:

Q.12.) Is there anything else that you would like to tell me about your experience of using the headsets?