James Paget University Hospitals NHS Foundation Trust

University of East Anglia

Information Sheet for Participants

Title of Project: **Investigating the Implementation in the NHS of an Immersive Virtual Reality System (NeuroVirt) for Optimising Arm Function After Stroke**

Thank you for taking the time to read this information sheet – we hope that you will consider taking part.

Invitation to Participate

You are invited to participate in a research study evaluating the implementation of NeuroVirt, an immersive virtual reality-based rehabilitation system, within NHS stroke services. Before deciding, please take the time to understand the study's purpose and what participation entails. Please read the following information sheet and feel free to discuss this with your family and friends. Please feel free to ask us any questions for further clarification.

Please note that participation in this study is entirely voluntary. If you choose not to take part, this will not affect the treatment you receive from your doctors, nurses, or therapists.

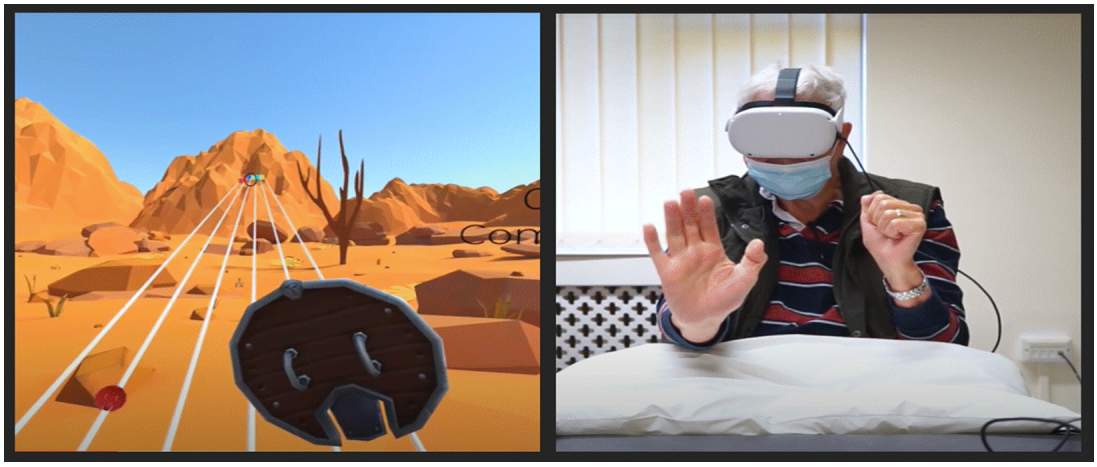
Purpose of the Study

In stroke survivors with upper limb (UL) impairments, about 80% of them are habitually not using their affected hand in their activities of daily living, which eventually results in developing the habit of not using the affected arm and hand. Given the slow recovery of hand function, both intensive and repetitive practice are considered to be essential ingredients of rehabilitation after stroke.

Since repetitive and intensive training can lead to meaningful recovery effects, and adherence to home-based therapy is crucial, we are investigating whether the implementation of immersive VR can be optimised within the clinical settings to

improve arm and hand function. Additionally, we aim to explore whether higher compliance rates can be achieved compared to usual care.

The NeuroVirt system is a new device that has been developed for people after stroke. It uses games that you can play within a virtual reality environment to encourage you to move your affected arm and hand. Immersive means that the system surrounds you with sights and sounds that make you feel like you are inside the game**.** You wear a headset that displays an interactive 3D virtual environment, which helps you stay focused and makes therapy sessions more engaging.



The first image shows an image of one of the games in NeuroVirt. The second image shows a stroke survivor lifting his hand and using the NeuroVirt system with a VR headset on his head.

You can also watch a short video of stroke survivors using the system at this link or scan the QR code. A transcription of the video is available alongside this sheet:

https://tinyurl.com/45hat34h

The objective of the study is to evaluate whether NeuroVirt can be effectively implemented into NHS stroke services. Specifically, the study aims to:

- Evaluate the effectiveness of implementation strategies for NeuroVirt within the NHS.
- Conduct an economic evaluation to understand the cost implications vs benefits of implementing NeuroVirt in the NHS.
- Identify barriers and enablers for the adoption of NeuroVirt in the NHS.
- Evaluate how well NeuroVirt performs in the NHS compared to usual care.

Study Design

This multi-centre implementation study includes a measure of cost-effectiveness and will be conducted in two phases:

- **Phase 1 (Control Phase):** An observational analysis at each site to understand usual care before introducing NeuroVirt across selected sites across the NHS England stroke rehabilitation pathways.
- **Phase 2 (Implementation Phase):** Gradual deployment of NeuroVirt using specific implementation strategies.

Why Have I Been Invited?

You are being invited because you have experienced a stroke resulting in upper limb impairment and are currently receiving inpatient rehabilitation. Your insights are valuable for understanding the implementation of NeuroVirt within NHS stroke care pathways as well as its impact. You are eligible to participate in the study because you meet the following criteria:

1. Have had a stroke (ischaemic or hemorrhagic) as an adult aged 18 years.
2. Have at least a little movement of the upper limb impairment but not have full dexterity; for example, you are able to lift your arm from your lap and

place it on a table in front of you but are unable to independently do up small buttons.

3. Can navigate the NeuroVirt device independently OR have a family member/carer/healthcare worker who will help with wearing the device.
4. Do not have photosensitive epilepsy or have not had an episode of photosensitive epilepsy within the last 12 months.
5. Have not been diagnosed with another neurological illness such as Parkinson's Disease or Multiple Sclerosis.
6. Do not have a frozen shoulder or any other musculoskeletal problems with your shoulder that would prevent you from using your affected arm in the study.
7. Are able to connect to WiFi at least every third day if using in an outpatient setting.

If you wish to participate in this study it will allow us to understand-

- What your experience while using NeuroVirt was like, for example, was it easy to use set-up and use at home or in the hospital?
- if you feel that NeuroVirt games could be useful for rehabilitation of your arm and hand?
- if NeuroVirt's implementation or use could be improved in any way (any advice/recommendations)

Do I Have to Take Part?

Participation is entirely voluntary. If you choose not to participate, your standard care will remain unaffected. You are free to withdraw from the study at any time without providing a reason, and this will not impact your ongoing care.

What Will Happen If I Take Part?

This project has two phases: an observational Control phase (**Phase 1**) and an Implementation phase (**Phase 2**). You will only be asked to participate in one of the phases.

If you are asked to participate in Phase 1, you will be asked to complete the following:

● **Completion of EQ-5D-5L Questionnaire** if this is not a part of your routine data collection (approximate time of completion 15-20 mins/ two sessions)**:** EQ-5D-5L assesses health-related quality of life across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It is simple and quick to complete, taking only a few minutes.

● **Completion of Arm Activity Measure, ArmA** (approximate time of completion 15-20 mins/ two sessions)**:** ArmA is a tool in the form of a patient-reported questionnaire to examine both active and passive motor functions among stroke patients with spasticity.

● **Completion of an Exercise Diary** if you are receiving outpatient rehabilitation (approximate time of completion 5 mins per day):

1. You will be asked to keep a daily diary for 10 days, recording the duration of arm exercises performed at home.
2. We will collect which home exercises you have been prescribed from your therapists.

If you are asked to participate in Phase 2, you will be asked to complete the following and take part in an interview:

- **Completion of EQ-5D-5L Questionnaire** if this is not a part of your routine data collection (approximate time of completion 15-20 mins/2 sessions): EQ-5D-5L assesses health-related quality of life across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It is simple and quick to complete, taking only a few minutes.

- **Completion of Arm Activity Measure, ArmA** (approximate time of completion 15-20 mins/ two sessions)**:** ArmA is a tool in the form of a patient-reported questionnaire to examine both active and passive motor functions among stroke patients with spasticity.

- **Completion of User Satisfaction Evaluation Questionnaire, USEQ** (approximate time of completion 5-10 mins/ two sessions)**:** USEQ is designed to evaluate how satisfied are the users who are receiving virtual rehabilitation systems.

- **Participation in Interview** (45 mins to 1 hour duration; will be held remotely via videoconferencing): You may be invited to share your experiences using the NeuroVirt system through an interview conducted via an online platform (such as Teams or Zoom). Both video and audio will be recorded and securely stored on the University of East Anglia's One Drive cloud. Transcripts will be anonymized using pseudonyms, and original recordings will be destroyed after verification. You will have the opportunity to review the transcripts if you wish.

What Are the Possible Benefits of Taking Part?

While personal benefits cannot be guaranteed, participation offers the opportunity to engage in virtual reality-based arm and hand training through games which may assist in your rehabilitation. Your feedback will contribute to the further

development of NeuroVirt, potentially aiding future stroke rehabilitation in an engaging manner. You will also have access to the study results for your records. Both control and implementation phases play crucial roles, and your contribution is valued equally, regardless of the phase.

Are There Any Possible Disadvantages or Risks in Taking Part?

The study interventions are designed to encourage intensive arm movement practice. You may take breaks as needed during exercises. However, increased movement might lead to discomfort or pain. If you experience pain or fatigue, please inform the therapist during their scheduled visits or weekly calls. They will assess and adjust your use of the NeuroVirt system accordingly. Should severe pain persist over three consecutive days, your participation in the study may be discontinued. In such cases, data collected up to that point will be retained, and you may still be invited to participate in interviews.

Some people have reported feeling motion sickness when using VR devices. The results of an earlier trial testing NeuroVirt showed that the average frame rate during sessions was 67.5 frames per second (fps). This is well above the industry standard minimum of 60 fps recommended for virtual reality devices. This helps prevent motion sickness and symptoms like dizziness, nausea, or headaches. By maintaining a high frame rate, the NeuroVirt system aims to reduce the likelihood of such symptoms.

How will we use information about you?

Please refer to this patient leaflet provided by the Health Research Authority. The leaflet gives information about:

- the legal basis for processing
- who will receive the data (outside of international transfers)
- more information about participants' rights

- contact details for the Information Commissioner's Office (for complaints)

Patient data and Research Leaflet: bit.ly/4naJwDW

We will need to use information from you for this research project. This information will include your:

- Name
- Contact details
- DOB
- Post-code
- Gender

We will need to use information from the NeuroVirt device for this research project. This information will include:

- The number of repetitions of movements,
- Time spent in virtual reality,
- Range of movement ability,
- Other technical data related to the NeuroVirt and hardware device.

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 or pseudonym instead.

James Paget University Hospitals NHS Foundation Trust (JPUH) is the sponsor of this research.

JPUH is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- The university who are helping run the study

We will keep all information about you safe and secure by:

- Using secure cloud-based storage
- Using lockable cabinets to keep paperwork in
- Using de-identified data including the way in which we register you on the NeuroVirt system

Your data will not be shared outside the UK.

How will we use the information after the study has stopped?

We will keep your study data for a maximum of 20 years. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. The study data will then be fully anonymised and securely archived in line with the JPUH Data Protection Policy.

What are your choices about how your information is used?

You can stop being part of the study at any time without giving a reason, but we will keep information about you that we already have. If you choose to withdraw then please inform Alvina Nawed (research associate), whose contact details are on page thirteen of this information sheet.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so we will tell you why we cannot do this.

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

Please contact Dr Kathryn Mares, whose contact details are at the end of this information sheet.

What Will Happen to the Results of the Research Study?

The results will be used to assess the implementation process and effectiveness of implementing NeuroVirt in NHS stroke services. Findings may be published in scientific journals and presented at medical and rehabilitation conferences. You will not be identified in any reports or publications. If you wish to receive a summary of the study results, please inform a member of the research team.

Data produced by the research team will be anonymised and shared with NeuroVirt, so they can better understand outcomes of the research generated with the NeuroVirt device. This information is being shared to improve future designs of the NeuroVirt device and virtual reality game platform. Some of this data will also contribute to a PhD for Mr Joseph Hartley-Palmer.

All equipment provided by Neurovirt for the study, including the VR headset (the "Neurovirt System"), remains the property of Neurovirt and must be returned at the end of the study.

Who Is Organising and Funding the Research?

This study is organised by the James Paget University Hospital in collaboration with selected NHS sites. It is funded by SBRI Healthcare, an NHS England initiative that supports the development of innovative technologies to address existing unmet

health needs within the NHS, such as improving rehabilitation outcomes after stroke.

Who Has Reviewed the Study?

The study has been reviewed and approved by an independent ethics committee to ensure it meets the necessary ethical standards.

What if I have a complaint or concern?

In the unlikely event of anything untoward happening you may complain to the Chief Investigator. Compensation arrangements for negligent harm are covered by the usual NHS Indemnity Insurance.

If you would like to discuss this study with someone who is not a part of the research team, then please contact:

Patient Advice and Liaison Service (PALS) by phone at ..t*o be completed by site*. or by email ..t*o be completed by site*..

Who is the study sponsor?

The James Paget University Hospitals NHS Foundation Trust (James Paget Hospital). The authorised person responsible for this trial can be contacted by email at h.hall@jpaget.nhs.uk.

Contact for Further Information

If you have any questions or require more information about the study, please contact:

Chief Investigator:

Dr Kathryn Mares

k.mares@uea.ac.uk

Research Associate:

Alvina Nawed

a.nawed@neurovirt.net