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Implementation of VR for upper limb rehabilitation after stroke (v1)

Submission date
03/09/2025

Recruitment status
Recruiting

Registration date
19/09/2025

Overall study status
Ongoing

Last Edited
19/09/2025

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is about finding out whether an immersive VR system called NeuroVirt can be effectively implemented within NHS stroke pathways to help stroke survivors with their arm recovery. It aims to do this by providing engaging, repetitive, game-based, high intensity arm movement training. The study will also look at how much it costs to use NeuroVirt and whether it improves therapy adherence and rehabilitation outcomes.

Aims:
To identify whether the implementation strategies are effective in facilitating the implementation of NeuroVirt UL in the NHS
To carry out an economic evaluation to understand the cost impact of implementing NeuroVirt in the NHS;
To identify the barriers and enablers to the uptake of NeuroVirt in the NHS

Who can participate?
• A stroke (ischaemic or hemorrhagic) in adults aged 18 years and above
• Have at least a little movement of the upper limb impairment but not have full dexterity; for example, they are able to lift their arm from their lap and place it on a table in front of them but are unable to independently do up small buttons.
• Can navigate the NeuroVirt device independently OR have a family member/carer/healthcare worker who will help with wearing the device.
• Be able to connect to WiFi at least every third day if using it at home

What does the study involve?
The study involves two phases:
Phase 1 (Observational phase): At each NHS site, the participants will continue their usual care, and data will be collected either through observation (if an inpatient) and exercise diaries (for patients receiving outpatient rehabilitation) for two weeks.
Participation will depend on the length of their inpatient rehabilitation stay or time receiving outpatient therapy.
Phase 2 (Implementation phase): Once the site has moved into the implementation phase, eligible participants will be introduced to the NeuroVirt system as part of their arm

rehabilitation. They will be encouraged to use the system regularly (as prescribed by their therapy team) over a period of minimum 4 weeks, for up to 2 hours/day. At the same time, they will continue to receive their usual arm therapy.

What are the possible benefits and risks of participating?
In phase 1 therapy will be provided as usual, however there is an additional burden for stroke survivors in that they will be asked to read a participant information sheet and sign consent for completion of the questionnaires at admission and discharge and complete arm exercise diaries for two weeks, if they are an outpatient. However, it will be made clear to them that they do not need to take part in this aspect of the study and that this will not affect their usual care. We have minimised the burden for completion of the diaries by making them quick to complete.
In phase 2 therapists will be trained to provide NeuroVirt. This is additional training and will take approximately two hours. Therapists will then prescribe NeuroVirt to their patients. This will not take any longer than they would typically take to create and prescribe an exercise programme but we have provided renumeration to the sites to compensate for the potential loss of therapy time through training and prescription of NeuroVirt. Therapists will be asked to consent to take part in either focus groups or interviews. They do not have to be part of these or any aspect of the study but should they do so will be offered a voucher to express our gratitude once focus groups and interviews have taken place.
Stroke survivors who use NeuroVirt will be asked to read a participant information sheet and sign consent for completion of the questionnaires at admission and discharge, complete arm exercise diaries for two weeks if they are an out-patient and take part in an online interview. It will be made clear to them however that they do not need to take part in this aspect of the study and that this will not affect their usual care.
Using NeuroVirt may lead to an increase in arm use by stroke survivors as individuals are hopefully more motivated to carry out their arm exercises. Stroke survivors who have not been using their affected arm may experience minor pain as a result of carrying out their exercises. If the pain persists for more than 1 hour after the exercise programme has stopped and it cannot be attributed to any other intervention, then the participant will be advised to stop exercising and to alert their therapist. This will be recorded as an adverse reaction. If pain persists for three consecutive days, then the participant may be removed from the study at the discretion of their therapist; all data will be retained should this occur. Similarly, any case/episode of motion sickness, will be reported as an adverse reaction. Also, to reduce the chances of fatigue, the participants will be informed that they can take breaks or stop at any time.

Where is the study run from?
James Paget University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2025 to May 2026

Who is funding the study?
SBRI Healthcare (UK)

Who is the main contact?
Dr Kathryn Mares, K.Mares@uea.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
356727

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 67815

Study information

Scientific Title
An evaluation of the implementation of an immersive virtual reality system (NeuroVirt) for optimising upper limb function after stroke

Study objectives
1. To identify whether the implementation strategies are effective in facilitating the implementation of NeuroVirt UL in the NHS
2. To carry out an economic evaluation to understand the cost impact of implementing NeuroVirt in the NHS
3. To identify the barriers and enablers to the uptake of NeuroVirt in the NHS
4. To refine the use of NeuroVirt within NHS settings

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/06/2025, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 207 104 8010 ; sheffield.rec@hra.nhs.uk), ref: 25/YH/0104

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke

Interventions
The study will take place in two stages.

Stage 1: Observing current arm therapy at each of our research sites
In the first stage, we will look at the current stroke rehabilitation services at 8 NHS inpatient and outpatient settings. We want to understand what usual arm therapy looks like, how much time patients spend on rehabilitation, and which clinicians or healthcare staff (therapists or others) are involved, and how much time they spend with patients.

Stage 2: Introducing NeuroVirt
In the second stage, we will gradually introduce NeuroVirt at each site. We will train a Clinical Champion who will cascade training to other clinical staff on how to use NeuroVirt. We will support therapists to integrate it into the rehabilitation plan for stroke survivors. We will keep track of how well the system is used and whether it improves adherence to arm exercises prescribed by the therapists.

How we will measure success:
We will use an implementation framework (RE-AIM framework) to measure how well NeuroVirt is working. This has five constructs and we will use the first four to measure success of our implementation.

Reach (how many stroke survivors use NeuroVirt): At least 60% of patients should follow the prescribed NeuroVirt exercises

Effectiveness (does NeuroVirt have an impact?): 60% of patients should show improvement in the game metrics recorded by NeuroVirt

Adoption (are therapists prepared to use NeuroVirt in their clinical practice): 80% of therapists should say they would continue using NeuroVirt after the study. This will be ascertained through focus groups

Implementation (consistent with the protocol): At least 80% of sites should follow the proper steps and adhere to the protocol when using NeuroVirt during the study. This will be measured by site surveys throughout the trial

Cost evaluation:
The study will also look at how much it costs to use NeuroVirt in NHS stroke services. We will compare this to the cost of the usual arm rehabilitation services. This will help us understand if NeuroVirt is a cost-effective way to implement arm rehabilitation after stroke.

How we will collect data:
Phase 1: This phase will involve collecting de-identified descriptive data of the included participants and sites and data from an observational analysis of current arm therapy including how it is usually carried out, time taken to complete arm therapy and who delivers it. This will be done through observations carried out by a research associate at inpatient settings and diary entries from participants with stroke who are receiving rehabilitation as outpatients. Any stroke survivor who is receiving arm therapy and who meets our inclusion criteria is eligible to take part and will be identified by their therapist.

Phase 2: During this phase we will collect de-identified descriptive data for stroke survivors who receive NeuroVirt. Participants will be identified as suitable by their therapist according to our previously tested inclusion criteria. We will track how well stroke survivors are using NeuroVirt through the system itself, which monitors adherence to the prescribed exercises, number of repetitions of various arm joints and progress in the games. We will also ask patients and therapists for feedback through questionnaires, online interviews and focus groups. We will carry out a second phase of observational analysis to understand concurrent therapy and see whether this changes once NeuroVirt is introduced. Stroke survivors in outpatient settings will complete a diary as per phase 1 for any arm therapy outside of the NeuroVirt system.

Additionally, we will ask stroke survivors who are receiving arm therapy to complete the following outcome measures:

Phase 1: EQ5D-5L, as a self-rated measure of health-related quality of life; ArmA, to evaluate difficulties in both passive and active upper limb function

Phase 2: EQ5D-5L; ArmA; and USEQ (User Satisfaction Evaluation Questionnaire), to evaluate how satisfied users are with the virtual rehabilitation system (NeuroVirt)

Health economics:
We will be collecting the following descriptive data for all patients admitted to the sites as part of the health economics study. This will be de-identified and presented as averages per site. It is not practicable or ethical to seek consent from every patient for this data as it does not enable identification of any one individual.

Gender – percentage male to female
Age – mean and standard deviation
NIHSS score – mean and standard deviation to indicate severity
Length of stay – mean and standard deviation
Type of care pathway – inpatient or community settings
Admissions per week
Number of patients with upper limb impairment
Profession
AFC band of staff (or seniority of consultants) delivering treatment

Who will be involved:
The study will involve stroke survivors and clinical staff (therapists) across the 8 NHS inpatient and outpatient settings. We plan to include at least 150 to 200 stroke survivors and around 30 therapists across all the settings.

Monitoring and analysis:
Throughout the study, we will regularly check that NeuroVirt is being used correctly and consistently. The research associate will conduct routine surveys at the NHS sites to monitor progress and adherence to the study protocol.

Involving patients and public:
This study follows on from our previous two clinical studies which incorporated extensive feedback from clinicians and stroke survivors, which has been used to shape this protocol. Our PPI lead and clinical staff from each site have been consulted in designing this study to make sure it is relevant and practical. We will continue to involve them as we gather and analyse the data to ensure that the findings are helpful and meaningful for everyone.

Conclusion:
This study will help us find out if NeuroVirt can be successfully integrated as an adjunct rehabilitation system for stroke recovery in the NHS, whether it's worth the cost, and what challenges might exist when trying to implement or use it.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
We will use an implementation framework (RE-AIM framework) to measure how well NeuroVirt is working, this has five constructs, and we will use the first four to measure success of our implementation:
RE-AIM framework:
1. Reach (how many stroke survivors use NeuroVirt): At least 60% of patients should follow the prescribed NeuroVirt exercises.
2. Effectiveness (does NeuroVirt have an impact?): 60% of patients should show improvement in the game metrics
recorded by NeuroVirt.
3. Adoption (are therapists prepared to use NeuroVirt in their clinical practice): 80% of therapists should say they would continue using NeuroVirt after the study. This will be ascertained through focus groups.
4. Implementation (consistent with the protocol): At least 80% of sites should follow the proper steps/adherence to the protocol when using NeuroVirt during the study. This will be measured by site surveys throughout the trial.

Additionally, participants will also complete the following outcome measures:
Phase 1:
1. EQ5D-5L: as a self-rated measure of health-related quality of life; collected at baseline and discharge from the hospital
2. Arm Activity Measure (ArmA): to evaluate difficulties in both passive and active upper limb function; collected at baseline and at discharge
Phase 2:
1. EQ5D-5L: as a self-rated measure of health-related quality of life; collected at baseline and discharge from the hospital
2. Arm Activity Measure (ArmA): to evaluate difficulties in both passive and active upper limb function; collected at baseline and at discharge

3. USEQ (User Satisfaction Evaluation Questionnaire): to evaluate how satisfied are the users who are receiving virtual rehabilitation systems (NeuroVirt), collected at the end of phase 2

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Sites delivering clinical services to stroke survivors
2. Therapists delivering upper limb therapy to stroke survivors
3. Stroke survivors meeting the following criteria:
3.1. A stroke (ischaemic or hemorrhagic) in adults aged above 18 years
3.2. Have at least a little movement of the upper limb impairment but not have full dexterity; for example,they are able to lift their arm from their lap and place it on a table in front of them but are unable to independently do up small buttons.
3.3. Can navigate the NeuroVirt device independently OR have a family member/carer /healthcare worker who will help with wearing the device.
3.4. Have at least a weak Wi-Fi connection at their home if recruited in the community rehabilitation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Stroke survivors:
1. Other neurological diagnoses including spinal stroke.
2. Communication,cognitive and language deficits,such as being unable to follow a one-stage command and providing informed consent.
3. Frozen shoulder or other impairments affecting the movement of their arm,such as arthritis or dislocation.
4. Any episode of photosensitive epilepsy within the last 12 months.
5. Presence of cerebral shunts.

Date of first enrolment

30/09/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Coast Community Healthcare CIC
Hamilton House, Battery Green Rd
Lowestoft
United Kingdom
NR32 1DE

Study participating centre
Norfolk Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Hertfordshire Community NHS Trust
Danesbury House neurological centre inpatient unit School Lane
Welwyn
United Kingdom
AL6 9PW

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Princess Royal Hospital, Lewes Rd
Haywards Heath
United Kingdom
RH16 4EX

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust
Queen Elizabeth Hospital
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Hinchingbrooke Hospital
Hinchingbrooke Park
Huntingdon
United Kingdom
PE29 6NT

Sponsor information

Organisation
James Paget University Hospitals NHS Foundation Trust

ROR
https://ror.org/04s7e3d74

Funder(s)

Funder type
Government

Funder Name
NHS England

Results and Publications

Individual participant data (IPD) sharing plan
Only members of the clinical team at participating NHS sites will have access to identifiable participant data. The participants will be allocated a unique user identification and pseudonym. The de-identified participant data will be stored securely on participating sites' secure cloud-based NHS systems during the study. During the trial all generated data will be stored in a cloud based online system managed by the James Paget University Hospital NHS Foundation Trust (sponsor site). At the end of the study, all of the participant's data, including consent forms and recorded interviews, will be destroyed. All anonymised data will be archived at the sponsor site (JPUH) for 20 years and then destroyed. Helen Hall (the representative at the sponsor site) and Dr Kathryn Mares (Chief Investigator) will be the custodian of the data and requests can be made to them to access the data for scholarly or research purposes only. The CI will work with JPUH to assess the appropriateness of each request on an individual basis.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4	01/07/2025	19/09/2025	No	Yes