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Feasibility of the implementation of an intensive upper-limb rehabilitation system (NeuroVirt) intervention for stroke survivors

Submission date 05/07/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/07/2023	**Overall study status** Completed	
Last Edited 04/01/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

One of the consequences of stroke is weakness or loss of movement in the arm. An important part of the treatment stroke survivors will receive following stroke are the exercises that are given to them by their therapist. These exercises are aimed at encouraging individuals to use their arm to help gain as much movement recovery as possible. Sometimes, though it is hard to stay motivated to do these exercises. The NeuroVirt system is a new device that has been developed for people after stroke. It uses games that stroke survivors can play within a virtual reality environment to encourage them to move their affected arm.

The NeuroVirt system may be better at motivating stroke survivors to move their affected arm and exercise it after a stroke. Therefore, by using NeuroVirt it may be possible to get better movement recovery of their arm. The researchers will test these theories out in a future trial but in this study, they want to find out whether the NeuroVirt system works as it was designed to and whether it will be possible to run a future trial. They also want to know what participants think about NeuroVirt.

Who can participate?

Patients aged 18 years old or older who have had a stroke (ischaemic or haemorrhagic) at least 3 months previously

What does the study involve?

Participants will be scheduled for three face-to-face appointments with the therapist during the study at Hobbs Rehabilitation Centre or patients will receive a home visit.

First appointment:

If eligible for the study, patients will be asked to sign a consent form to take part in the study. Once this has been signed, then the therapist will carry out a number of clinical assessments to find out how well participants are able to move their arm. Participants will be asked additional questions about pain and fatigue. One of the assessments will include using the NeuroVirt device to measure the range of movement so that the therapist will also be able to see whether participants can wear the virtual reality (VR) headset independently and navigate to the Wi-Fi

settings. This visit is expected to take about 90 minutes. After this appointment participants will be randomly allocated to either the NeuroVirt group or the control group. The control group will receive an exercise prescription on paper.

Second appointment:
The second appointment will take place shortly after the first appointment. At this appointment participants will receive instruction on how to use NeuroVirt or participants will receive an exercise prescription on paper depending on the allocation group. This visit is expected to take about 90 minutes.

NeuroVirt intervention:
Participants allocated to NeuroVirt will be prescribed a programme of games that they will need to complete. The therapist will provide participants with a warm-up which will last 15 minutes and then games on the NeuroVirt system that will last 45 minutes. Participants will need to complete this twice a day, 6 days a week for 6 weeks. Participants will be provided with written and video instructions on how to set up and run it at home. After each time participants use the NeuroVirt system it will prompt them to record how they are feeling. Participants will be asked to rate their pain and fatigue level after they complete each VR session. The device will remotely collect information such as how often participants need to remove the headset when they are using it, how long they are using the device for and any technical issues such as loss of Wi-Fi connection.

Control group:
Participants allocated to the control group will receive exercises on paper, then the therapist will demonstrate all the exercises and check that participants are able to do all of them.
The therapist will provide participants with a warm-up which will last 15 minutes and then exercises that will last 45 minutes. Participants will need to complete this twice a day, 6 days a week for 6 weeks. Participants will be provided with a diary to record whether they do their exercises or not. Therapists will ring each participant once a week at a time convenient to them and within the working hours of 8.30 to 16.30, Monday to Friday. The therapist will respond to any questions and receive feedback on the use of the device or exercise program.

Third Appointment:
When participants have completed 6 weeks of arm training with either the NeuroVirt system or with the exercises prescribed on paper the researchers will arrange a final face-to-face appointment at the Hobbs Rehabilitation Centre or a home visit. During this visit they will repeat the clinical assessments that were done at the beginning of the study. The researchers are interested in the participants' experiences of using the NeuroVirt system so whilst they are at the centre we will interview them about what they liked or didn’t like about the system. The researchers will record the interviews with a voice recorder.

What are the possible risks and benefits of participating?
During its development, NeuroVirt has already been trialled by healthcare professionals and 40 stroke survivors. As the researchers are still testing the NeuroVirt system, they cannot promise that taking part will benefit a participant but they will get to try Virtual Reality that allows arm training through rehabilitation games. Participants' feedback may help further the development of this device and could potentially help stroke survivors rehabilitate in a fun and engaging way. The NeuroVirt system aims to stimulate the intensive practice of arm movements. There is the possibility that a participant may experience some pain or an increase in pain because of moving their arm more than they probably have been doing. If this occurs, then a therapist will review their use of the NeuroVirt system. If the pain is severe and occurs over three consecutive days, then the researchers may stop their participation in the study.

Where is the study run from?
The study is being run from two Hobbs Rehabilitation Centres in Bristol and Winchester, or in Norfolk in participants own homes and the research is being sponsored by the University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
June 2023 to June 2024

Who is funding the study?
The study is funded by an NHS England initiative called SBRI Healthcare (UK)

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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
330780

Central Portfolio Management System (CPMS)
57572

Study information

Scientific Title
Feasibility of the implementation of an intensive upper-limb rehabilitation system (NeuroVirt) intervention for stroke survivors: a randomized controlled feasibility study

Study objectives
Is a novel technological platform designed to improve hand and arm function through the NeuroVirt training programme feasible for people after stroke to use in their own homes?

Aim: to assess the feasibility of conducting a future pragmatic, randomised controlled trial to test the use of the NeuroVirt training programme in people's own homes to support hand and arm recovery following a stroke.

Objectives:
1. To provide evidence of the potential for clinical efficacy of Neurovirt versus usual care
2. Willingness to be randomised to either intervention
3. Feasibility of recruiting and retaining eligible people following a stroke
4. Adherence to the study protocol
5. Appropriateness of clinical outcome measures in identifying improved hand and arm function
6. To understand the stroke survivor's experiences of participating in the trial, including acceptability, barriers and enablers of receiving the intervention
7. To understand what the impact on a caregiver may be
8. To refine the Neurovirt programme or other aspects of the intervention based on feedback.
9. To refine patient training materials

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/06/2023, University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Subcommittee (Norwich Research Park, Norwich, NR4 7TJ, United Kingdom; No telephone number; ethicsapproval@uea.ac.uk), ref: ETH2223-1987

Primary study design
Interventional

Study design
Multi-site randomized assessor-blind clinical trial

Study type(s)
Other

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

Interventions
Participants will be randomized to either NeuroVirt or the control group via a computer-generated system and will be administered by someone who is not directly connected to the research team.

Control group: the control group will be provided with a personalised upper limb exercise plan designed by the therapist. The control group will undertake up to two 1-hour sessions each day, 6 days a week for 6 weeks.

Experimental group: the experimental group will use an immersive virtual reality (VR) platform that is designed to encourage high-dose upper-limb training via fun and motivational games (NeuroVirt). Participants will undertake up to two 1-hour sessions each day, 6 days a week for 6 weeks. At the end of the 6 weeks they return the device and take part in interviews.

Throughout the 6-week intervention period, participants in the control group and experimental group will receive a weekly phone call which will last usually 10-15 minutes from the therapist. They will be asked a standardised set of questions to ensure that they are managing the programme and to give them the opportunity to raise any concerns. The researchers will also use this opportunity to monitor safety.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Neurovirt

Primary outcome(s)
Upper limb motor performance is measured using Fugl Meyer - Upper Extremity at baseline and at the end of the 6-week intervention period

Key secondary outcome(s)
1. Recruitment rates measured by multiplying the number of sites and randomized patients per site by the number of months of recruitment time, and attrition measured by the attrition rate at 6 weeks.
2. Adherence will be measured via NeuroVirt or the diaries completed by participants in the control group
3. Upper limb range of movement measurements from NeuroVirt at baseline and at the end of the 6-week intervention period
4. Grip strength measured with a dynamometer at baseline and at the end of the 6-week intervention period
5. Upper limb function measured with Action Research Arm Test at baseline and at the end of the 6-week intervention period
6. Activity in the hemiparetic arm measured with arm activity measure (Arm A) at baseline and at the end of the 6-week intervention period

7. Health-related quality of life measured using EQ5D-5L at baseline and at the end of the 6-week intervention period
8. Fatigue will be measured using the Fatigue Assessment Scale at baseline and at the end of the 6-week intervention period
9. Pain will be measured using Pain Visual Analogue Scale at baseline and at the end of the 6-week intervention period
10. Useability and acceptability assessed via interviews at 6 weeks
11. Adverse events will be measured using the adverse event reporting form Version 1 at 6 weeks

Completion date
28/06/2024

Eligibility

Key inclusion criteria
1. A stroke (ischaemic or haemorrhagic) at least 3 months previously
2. Have at least a little motion of the upper limb impairment but not have full dexterity i.e. be able to lift their arm from their lap and place it on a table in front of them but not be able to stack 5 five pence coins
3. Can navigate the NeuroVirt device independently on the first trial day OR has a family member /carer on a daily basis that can help with wearing the device at the patient’s home independently
4. Has at least a weak Wifi connection at their home
5. Live within around 1 hour's travelling distance of Norwich Community Hospital if being recruited from Norfolk or Suffolk
6. 18 years of age or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Other neurological diagnoses
2. Communication, cognitive and language deficits such that they are unable to follow a one-stage command and give informed consent
3. Frozen shoulder or other impairments affecting the movement of their arm such as arthritis
4. Any episode of photosensitive epilepsy within the last 12 months
5. Refuse to consent to GP being contacted

Date of first enrolment
12/07/2023

Date of final enrolment
30/03/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hobbs Rehabilitation
80 Macrae Road
Ham Green
Pill
Bristol
United Kingdom
BS20 0DD

Study participating centre
Hobbs Rehabilitation
Unit 1, Bridgets Farm Offices
Bridgetts Lane
Martyr Worthy
Winchester
United Kingdom
SO21 1AR

Study participating centre
University of East Anglia
Earlham Road
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation

University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Other

Funder Name
SBRI Healthcare – the Small Business Research Initiative

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated during and/or analysed during the current study will be stored in a non-publicly available repository hosted by the University of East Anglia. Data will be anonymised and available on request from Dr Kathryn Mares (k.mares@uea.ac.uk).
Descriptive data including age, date of stroke, sex and ethnicity will be stored. Interview transcripts and adverse events will be stored. This data will be available no earlier than 12 months after project completion. Data requests will be considered on a case-by-case basis and at the discretion of Dr Kathryn Mares and the Research and Innovation team at the University of East Anglia. Consent from participants has been obtained. Anonymised data will be destroyed after 10 years.

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