ISRCTN46051085 https://doi.org/10.1186/ISRCTN46051085

Is the implementation of an intensive arm rehabilitation system (NeuroVirt) feasible for people after stroke?

Submission date
08/02/2023

Recruitment status
No longer recruiting

Registration date
24/02/2023

Overall study status
Completed

Last Edited
09/02/2023

Condition category
Nervous System Diseases

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

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.
We think that the NeuroVirt system may be better at motivating stroke survivors to move their affected arm and exercise it after stroke. Therefore, by using NeuroVirt it may be possible to get better movement recovery of their arm. We will test these theories out in a future trial but in this study, we want to find out whether the NeuroVirt system works as it was designed to. We want to know if it will work when several people are using the system at the same time and whether it functions properly within a stroke survivor's own home. We also want to know what people taking part in the trial think about NeuroVirt.

Who can participate?
We are including 12 people who have:
1. Had a stroke (ischaemic or haemorrhagic) at least 3-months previously;
2. Have at least a little motion of the affected arm but not have full dexterity i.e. be able to lift their arm from their lap and place on a table in front of them but not be able to stack 5 £1 coins.
3. Can navigate the NeuroVirt device independently following a trial during the first day with a researcher present
4. Can demonstrate wearing the NeuroVirt device independently at 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.
5. Has at least a weak Wifi connection at their home
We are excluding people who have:
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

What does the study involve?
If eligible to be recruited to the study then participants would be invited to attend an assessment at a site rehabilitation centre closest to them. At that visit they will be asked to sign an informed consent form and then will complete an assessment with a therapist.
To assess whether a participant can use the device at home they will be asked to trial the NeuroVirt system. They will be asked to try and wear the virtual reality (VR) headset independently and navigate to the Wi-Fi settings and games.
They will then be guided on how to wear the device independently and how to access the games and Wi-Fi settings in the same manner that they would need to do when they take the device home for the first time.
Each participant will be provided with written and video instructions on how to set-up and run the device at home.
The aim of the NeuroVirt system is to provide intensive movement practice of the affected arm. The therapist will therefore prescribe a programme of games lasting 45 minutes that will need to be completed twice a day, six days a week for six weeks. They will also provide each participant with a warm-up which will last 15 minutes and which should be completed before starting the games.
After each use the NeuroVirt system will prompt the participant to record how they are feeling. They will be asked to rate their pain and fatigue level after each session. If the pain or fatigue levels increase by a specific threshold defined by the therapist, the device will lock and will not be useable until a phone call with the therapist within the week. The therapist will then reassess whether the participant may carry on using the device.
We are interested in how well the NeuroVirt system works in people's home, so the device will remotely collect information such as how often they 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.
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 in that week.
Once a participant has completed six weeks of arm training with the NeuroVirt system we will ask them to return to the rehabilitation centre to return the device. We are interested in their 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. We 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 we are still testing the NeuroVirt system however, we cannot promise that taking part will benefit a participant but they will get to try Virtual Reality that allows arm training through rehabilitation games. Thier feedback may help further development of this device and could potentially help stroke survivors rehabilitate in a fun and engaging way.
The NeuroVirt system aims to stimulate 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 we 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 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?
January 2023 to May 2023

Who is funding the study?
National Institute of Health Research as part of the i4i Connect fund (UK)

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

Contact information

Type(s)
Principal investigator

Contact name
Dr Kathryn Mares

ORCID ID
https://orcid.org/0000-0003-3923-4472

Contact details
School of Health Sciences
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 1603593891
k.mares@uea.ac.uk

Additional identifiers

Study information

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

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 for 6-weeks?
Aim: to assess the technical feasibility, useability and acceptability of delivering a 6-week upper-limb rehabilitation intervention with the use of the NeuroVirt system in people's own homes.
Objectives:
1. To understand the technical back-end issues and risks (i.e Wi-fi, data loss, data projection, technical delays in frames per second etc) if any, are encountered when multiple NeuroVirt

devices are in concurrent operation by patients in their homes over a 6-week intervention period.
2. To assess whether patients can learn to navigate the Virtual Reality system independently to rehabilitate daily for 6 weeks.
3. To assess the rate of completing developed rehabilitation material provided in Virtual Reality (providing evidence of how much material is required for the follow-up study and how long new VR material will last).
4. To gain feedback on training materials (visual, documented, technical) for efficient set-up.
5. To refine the implementation of the intervention based on feedback.
6. To refine the research protocol based on feedback.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/01/2023, University of East Anglia (Norwich Research Park, Norwich, NR4 7TJ, UK; no telephone number provided; ethicsapproval@uea.ac.uk), ref: ETH2223-0962

Primary study design
Interventional

Study design
Single centre pre-post feasibility study

Study type(s)
Other

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

Interventions
An immersive virtual reality (VR) platform that is designed to encourage high-dose upper-limb training via fun and motivational games (NeuroVirt).

Participants are given NeuroVirt to take away and use at home for six weeks. They are prescribed upper limb exercises using the NeuroVirt device which have to be completed for 45 minutes twice a day for six days a week for six weeks. At the end of the six weeks they return the device and take part in interviews.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Technical issues including backend stability, average wi-fi connection stability, stability on rendered frames per second and number of times participant removes headset during the session at 6 weeks measured using the NeuroVirt headset.

Key secondary outcome(s)
1. Duration of rehabilitation material measured by length of time to complete each level of game at 6 weeks.
2. Useability and acceptability via interviews at 6 weeks
3. Adverse events at 6 weeks

Completion date
15/05/2023

Eligibility

Key inclusion criteria
1. Diagnosed with 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 on a table in front of them but not be able to stack 5 £1 coins.
3. Can navigate the NeuroVirt device independently following a trial during the first day with a researcher present
4. Can demonstrate wearing the NeuroVirt device independently at 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.
5. Has at least a weak Wifi connection at their home

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

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
27/02/2023

Date of final enrolment
31/03/2023

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

Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sets generated during the 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 the 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	17/01/2023	09/02/2023	No	Yes