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

We invite you to take part in this research study.

- Before you decide please take the time to read through this information sheet. Please feel free to discuss this with family and friends.
- You are free to decide not to take part in this study. If you choose not to then this will not affect the treatment you receive from doctors, nurses or therapists.
- Please ask us if you are unsure or have any questions.

Important things to know.

- We want to find out how you feel about using the NeuroVirt system. This uses immersive virtual reality games made specifically for rehabilitation of the arm following a stroke.
- We want to know whether the NeuroVirt system works well within your home.
- We want to understand what you think about being involved in this study.

How to contact us

To find out more:

Dr Kathryn Mares
Chief Investigator
k.mares@uea.ac.uk

or

Mrs Alison Watt
Research Physiotherapist /Physiotherapist /Principle Investigator
alisonwatt@hobbsrehabilitation.co.uk

To make a complaint:

Dr Kathryn Mares
Chief Investigator
k.mares@uea.ac.uk

1. What is the study's purpose?

One of the consequences of stroke is weakness or loss of movement in the arm. An important part of the treatment you will receive following stroke is the exercises that will be given to you by your therapist. These exercises are aimed at encouraging you to use your arm and will help you 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 you can play within a virtual reality environment to encourage you to move your affected arm.

The picture below shows a stroke survivor using the NeuroVirt system, he is wearing virtual reality goggles in order to access the games. The picture on the left shows an image of one of the games that you can play in the virtual reality environment. You can also watch a short video of stroke survivors using the system at this link: https://drive.google.com/file/d/1OFaWzVGaN3O47IqYbNM7nGFlMsr5CA6e/view

We think that the NeuroVirt system may be better at motivating you to move your affected arm and exercise it after stroke. Therefore, by using NeuroVirt it may be possible to get better recovery of your 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 your home. We also want to know what you think about NeuroVirt.

2. Why am I being asked to take part

You are being asked to take part because:

- You have previously consented to be contacted by Hobbs Rehabilitation about opportunities for participating in research.
- You have had a first stroke at least three months ago
- You have had a stroke which is affecting your arm and you still have problems moving your arm. You can lift your arm from your lap to a table when sitting but you cannot stack five £1 coins.
- You can give consent to take part
- You have at least a weak Wi-Fi connection at your home
- You do not have photosensitive epilepsy or have not had an episode of photosensitive epilepsy within the last 12 months.
- You have not been diagnosed with another neurological illness
- You 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.
- You can put the headset on and access the games or have someone at home who can help you.

3. What will happen to me if I take part?

If you decide to take part, you will complete our 'consent to contact' form and return it via post or email. We will then contact you and invite you to attend an assessment at a Hobbs Rehabilitation Centre. This will be at their centre in either Bristol or Winchester, whichever is the closest to you. If you feel that you will need someone to help you use the NeuroVirt system, then we would ask that they accompany you on this visit.

Bristol Centre	**Winchester Centre**
80 Macrae Road Ham Green Pill Bristol BS20 0DD	Bridgetts Lane Martyr Worthy Winchester SO21 1AR

When you get to the centre one of the physiotherapists will answer any questions you might have about the study, and you will be asked to sign a consent form.

Once this has been signed then the physiotherapist will carry out an assessment of how well you are able to move your arm. They will also ask you some questions about any pain or fatigue you may be experiencing.

To assess whether you can use the device at home you will be asked to trial the NeuroVirt system. You will be asked to try and wear the virtual reality (VR) headset independently and navigate to the Wi-Fi settings and games. Before each game the VR has a calibration process that measures your ability to perform each movement before you enter the game.

You 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 you would need to do when you take the device home for the first time. If you are unable to do this, then unfortunately you will not be able to take part in the study.

If you are able to take part in the study, then you will be provided with written and video instructions on how to set-up and run the device at home. If you encounter any technical issues a NeuroVirt team member will be available for a call to support, you whilst setting up.

We expect this first visit to take around 90 minutes.

The aim of the NeuroVirt system is to provide intensive movement practice of your affected arm. The physiotherapist will therefore prescribe a programme of games that you will need to complete. They will provide you with a warm-up which will last 15 minutes and then games on the NeuroVirt system that will last 45 minutes. You will need to complete this twice a day, six days a week for six weeks.

After each time you use the NeuroVirt system it will prompt you to record how you are feeling. You will be asked to rate your pain and fatigue level after you complete each VR session. If your pain or fatigue levels increase by a specific threshold defined by the physiotherapist, the device will lock and will not be useable until you have your next call with the physiotherapist within the week. The physiotherapist will assess whether you may carry on using the device.

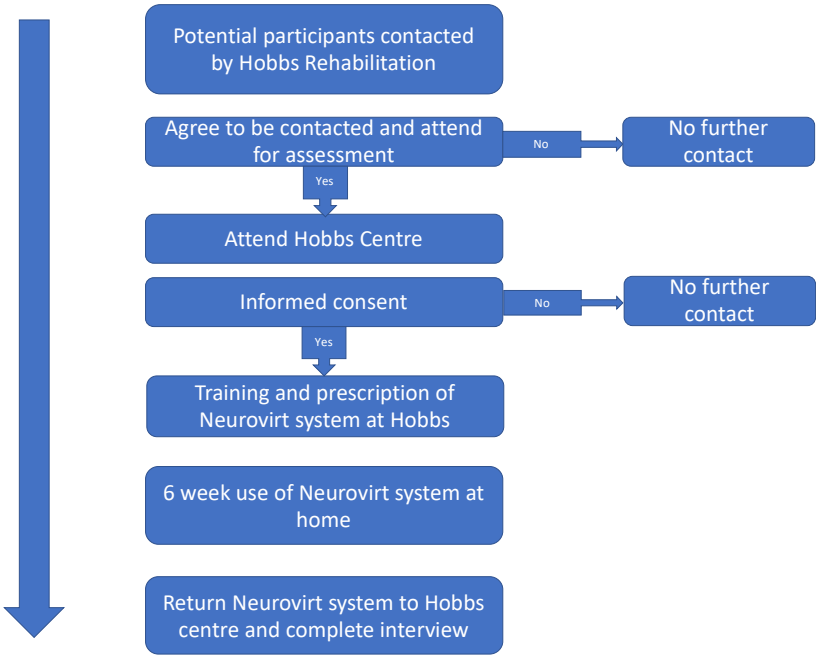
We are interested in how well the NeuroVirt system works in your home, so the device will remotely collect information such as how often you need to remove the headset when you are using it, how long you are using the device for and any technical issues such as loss of Wi-Fi connection.

We will ring you once a week at a time convenient to you within the working hours of 8.30 to 16.30, Monday to Friday. A Hobbs Rehabilitation physiotherapist will call you to respond to any questions you may have and receive your feedback on the use of the device in that week.

If at any time you are worried about using the NeuroVirt system then stop using it and you can either contact us via telephone within the working hours of 8.30 to 16.30, Monday to Friday or you can wait to discuss your concerns when we ring you.

When you have completed six weeks of arm training with the NeuroVirt system we will ask you to return to the Hobbs centre to return the device. We are interested in your experiences of using the NeuroVirt system. Whilst you are at the centre we will interview you about what you liked or didn't like about the system. We will record the interviews with a voice recorder. This visit will take approximately 60 minutes.

The flow chart below shows the process for this study:



4. Do I have to take part?

No, taking part is entirely voluntary. If you decide not to take part, your care will not be affected in any way. You are free to withdraw from the study at any time. If you do decide to withdraw, it will not affect your level of other healthcare. Although it would be helpful to know the reason why you withdrew,

you are under no obligation to tell us. Any data that we may have collected from you before you withdrew, will used in the final analysis, unless you tell us you do not want it to be used. If this is the case then please inform Mrs Alison Watt, whose contact details are on page one of this information sheet.

5. What are the possible benefits of taking part?

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 you but if you do take part in the study you will get to try Virtual Reality that allows arm training through rehabilitation games. Your feedback may help further development of this device and could potentially help stroke survivors rehabilitate in a fun and engaging way. You will also have access to the results of the research if you wish to have them for your records.

6. Are there any possible disadvantages or risk if I take part?

The NeuroVirt system aims to stimulate intensive practice of arm movements. If you want a rest at any time during the completion of your exercises using NeuroVirt you can take as many breaks as you need.

There is the possibility that you may experience some pain or an increase in pain because of moving your arm more than you probably have been doing. If this occurs, then it is very important that you talk to the physiotherapist about this when they ring you. They will then review your use of the NeuroVirt system. If the pain is severe and occurs over three consecutive days, then we may stop your participation in the study. If this occurs, then we will keep any data that we have gained up to this point. We may also still ask you to take part in the interviews. Should you be concerned then you are also at liberty to call your GP or use the NHS 111 service.

If you do not return the NeuroVirt system at the end of the study we will telephone you to arrange a time to pick it up or for you to bring it in. As a final resort if there is no response then we will then contact the police.

7. Expenses

We will reimburse you for all travel expenses related to travelling to and from the rehabilitation centres.

8. Payment

As a thank you for your time in taking part in this study we would like to offer you a payment via an Amazon voucher of £100. You are eligible for this payment once your involvement in the study is at an end (this is most likely to be after your interview). If you would like to receive the payment, please read through the supplementary information we have attached to this information sheet as this payment may affect any welfare benefits that you are in receipt of.

9. What if I have a complaint or concern?

In the unlikely event of anything untoward happening you may complain to the Chief Investigator or to the Principal Investigator. Compensation arrangements for negligent harm are covered by Hobbs Rehabilitation and university indemnity.

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

Dr Kenda Crozier
Interim Head of School
School of Health Sciences
University of East Anglia
NR4 7TJ
k.crozier@uea.ac.uk

10. Who will know I am taking part in the study?

Following your signed consent, we will write to your GP to let them know you are taking part in the study. We will also record this in your notes held by Hobbs Rehabilitation. We will not tell anyone else you are taking part in the study unless we are worried that your health and well-being are at risk. We will inform you if for safeguarding reasons we need to disclose your information. Only those people who require this information as part of maintaining your safety will be informed.

All information collected about you during the study will be kept strictly confidential and in compliance with GDPR. You will be allocated a unique user

identification and pseudonym. All data collected will be de-identfied using this identifier and pseudonym including the interviews. This will also be used to register you on the NeuroVirt system.

Data generated by the NeuroVirt device includes the number of repetitions of movements, time spent in virtual reality, and range of movement ability, as well as other technical data related to the NeuroVirt and hardware device. This information will be gathered and then securely saved in a secure cloud-based system. We consider this sensitive data and will use a Data Privacy Protocol, a way of ensuring your data is protected when it is sent through the internet.

11. What happens at the end of the study?

All personal data including consent forms and the recordings of the interviews will be destroyed at the end of the study. At this point the data we have collected for the purposes of research will be anonymous. This anonymised data will be stored securely by the University of East Anglia for ten years so that we can access it in the future if we need to. After this it will also be destroyed.

Data produced by the research team will be anonymised and shared between NeuroVirt, UEA and Hobbs Rehabilitation 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. We will also write up the findings of this study for a scientific journal and present this work at medical and rehabilitation conferences.

You can be provided with a summary of the findings from this research if you would like.

If you would like to see the data management and privacy policies for Hobbs Rehabilitation, NeuroVirt or the University of East Anglia please contact Dr Kathryn Mares.

12. Who is organising and funding the research?

The study is being funded by the National Institute of Health Research as part of the i4i Connect fund and is organised by a research team at the University of East Anglia in collaboration with Hobbs Rehabilitation.

13. What if I have a complaint or concern?

In the unlikely event of anything untoward happening you may complain to the Chief Investigator, or directly to the university to Dr Kenda Crozier as above.

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