VIRTUE: Virtual reality based Cognitive Rehabilitation immediately after a stroke

A randomised controlled trial to identify the optimum dosing and acceptability of Virtual Reality based treatment.

We invite you to take part in a research study

- You are being invited to take part in a research study because you have recently had a stroke.
- Before you decide, it is essential for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully and discuss it with friends and family if you wish. You are free to decide whether or not to take part in this trial. If you choose not to take part, this will not affect the care you get from the stroke team.
- In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
- Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
- At the end of the study we will save some of the data in case we need to check itfor future research. We will make sure no-one can work out who you are from the reports we write.
- Please feel free to contact us if there is anything that is unclear or if you would like more information.

Important things you need to know

- We want to find out if there is a useful amount of virtual reality immersion that could benefit cognitive rehabilitation
- We want to find ways to improve the amount and quality of cognitive rehabilitation using new and exciting technology.
- We are testing the acceptability of Virtual Reality immersion immediately after a stroke

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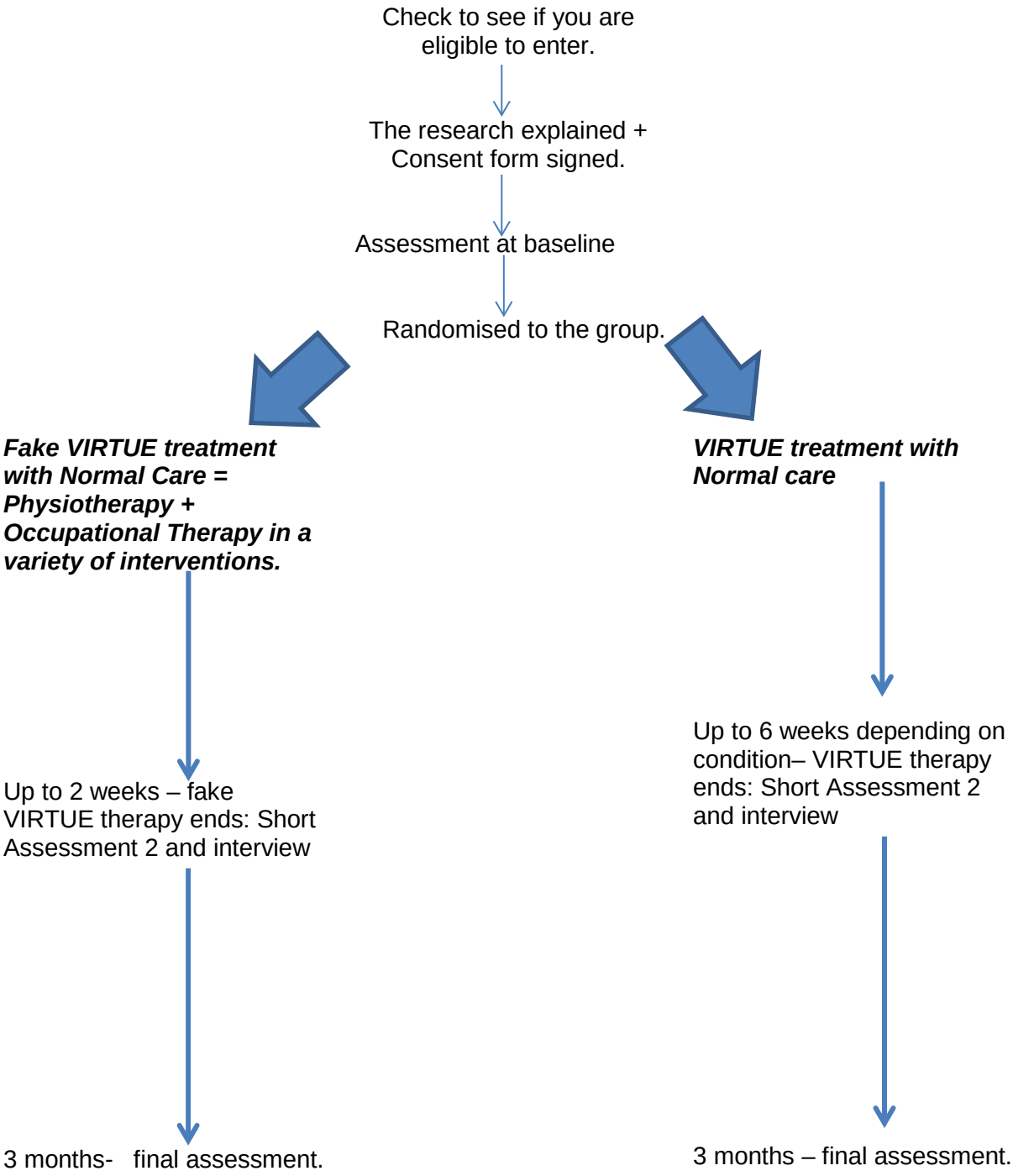
VIRTUE Study: At a glance



1) Why are we doing this study?

Virtual Reality (VR) has previously been tested with neurological patients, but its usefulness as a tool for cognitive rehabilitation after stroke is still mostly unknown. We want to address this question as an important step towards improving the quality and efficiency of cognitive rehabilitation.

2) What do I need to know about the technology used in this study?

When the participant is wearing a virtual reality headset, they are immersed in a virtual environment. The treatment will take place either at the bedside or in the therapy treatment room. The VR can be used in a wheelchair, armchair, lying on the plinth or in bed. The participant is then able to interact with objects within the environment using either one or two hand controllers. Using the headset and controller, a series of scenarios that resemble activities done everday, can be practised, for example: making toast, selecting items at a cafe, or paying a cashier. This approach could potentially allow the patient to get more rehabilitation time, practice sequencing, memory, problem-solving and visual scanning activities without risk of injury.

3) Why am I being asked to take part?

You have been asked because you have been diagnosed as having a stroke within the last three weeks that has affected your cognitive functioning. It is up to you to decide whether or not to take part. Up to 60 Participants will be in this study.

4) What will I need to do if I take part?

If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

You will be randomly chosen to either receive VIRTUE or Fake VIRTUE. Both involve wearing the VR headset, with support from a research therapy assistant, five times a week for a maximum of 45minutes for a duration depending on your condition. This treatment can take place in the therapy gym, or at the bedside. This will be in addition to your usual therapy routine.

A series of assessments, both paper-based and practical will take place before starting the VIRTUE treatment, at the end of VIRTUE treatment and at three month follow up.

5) What are the possible benefits or side effects?

One of the possible benefits that could occur from taking part in this study is the increased recovery rate of cognitive abilities.
The results will be used to further develop the use of Virtual Reality technologies for cognitive rehabilitation.

There is a potential risk of experiencing a side effect of VR called cyber-sickness, which present similar symptoms to motion sickness. If this does occur, the participant can ask for the headset to be removed immediately.

6) What happens when the trial ends?

The headset will be returned to the University of Chester, and all of the data collected will be analysed anonymously. The results may then be published in a medical journal, and the VIRTUE application will be further developed into a commercial product.

We will need to use information from you and from your medical records, Sentinel Stroke National Audit Programme (SSNAP), and stroke register for this research project.

This information will include your NHS number, hospital number, date of birth, name and contact details. 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 instead. We will keep all information about you safe and secure.

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.

7) 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 stop taking part in the study, we would like to continue collecting information about your health from your hospital records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet provided (Transparency Leaflet v2, dated 19/09/2019)
- by asking one of the research team
- by sending an email to kausikchatterjee@nhs.net or
- by ringing Dr Chatterjee on 01244 362168.

9) What if there is a problem?

If you have a complaint about your treatment by members of staff (doctors, nurses or a therapist) you should complain through the usual NHS complaints system-

- Patients Advice and Liaison Service (PALS) Freephone 0800 195 1241 and select option 2 or phone 01244 366066
- Email PALS: cochpals@nhs.net or
- Write to PALS Manager, PALS, Countess of Chester Hospital Foundation Trust, Liverpool Road, Chester CH2 1UL

If you have a complaint about the VIRTUE Study, you should contact Dr Chatterjee. If a serious adverse event occurs, Dr Chatterjee will report this to the sponsor of the study (Countess of Chester Hospital).

Complaints regarding how researchers have handled your information can be directed to the Information Commissioner's Office (ICO) - 0303 123 1113. Please refer to GDPR leaflet provided.

The local R&D committee reviews all research taking place in the Trust and the NHS National Research Committee (REC) scrutinises all research undertaken on patients.