PARTICIPANT INFORMATION SHEET

A pilot study investigating the use of Virtual Reality with "Etee" on finger function in post-stroke survivors.

We would like to invite you to take part in this study, before you decide you need to understand why the research is being done and what would be required of you. It is completely up to you whether you want to take part or not. Please take the time to read this document carefully and ask questions if you are unsure about any part of this study.

1. Background

VR allows a person to interact within a virtual world through a device. Research suggests that VR can be used in some post-stroke patients to help improve recovery of muscle control. The purpose of this study is to examine how feasible & useful using VR is in relation to another method used to help improve finger function in stroke survivors. This study is a collaborative project which is being supported by University of South Wales, KESS, & Tengi0.

2. Why have I been invited?

You have been invited to take part in this study as you have signed up for the Stroke Hub Wales research network. The types of people we would like to hear from:

1) are over 18 years old.
2) can give informed consent.
3) are 3 months or more post-stroke
4) have reduced control in one hand
5) have access to the internet and a windows laptop or computer
6) can understand and read English
7) do not have any great problems with their vision
8) do not have any history of motion sickness
9) do not have Aphasia. (Aphasia is when a person has difficulty with their language or speech).
10) are not using the Nine-Hole Peg test (9HPT) as part of their usual care/ rehabilitation.

Unfortunately, we are unable to include individuals with Aphasia, visual problems, or motion sickness at this point.

3. What will happen if you decide to participate?

You will be invited to a 30-minute meeting where we will answer any questions you may have. In addition, we will give you some simple tasks (Star cancellation test & wooden

peg, which will be inside the information pack) to see if you can do what is required in the study. Feel free to ask any questions. If everything is ok for you to take part, you will need to sign two consent form and return one to us. You will then be randomly placed into one of the following groups:

Group 1 Virtual reality + Usual Care	Group 2 Nine-Hole peg test + Usual Care	Group 3 Usual care

Usual care refers to activities you have been prescribed by your medical practitioner/ Physiotherapist. It is important that all groups continue usual care as normal throughout this study. We will arrange to send any equipment you may need and inform you of the delivery date of any materials we send by post, delivery can be arranged to suit you.

Once the equipment has been delivered, you will be invited to a tutorial where we will measure your finger function and go through how to use any equipment you have been sent, this will take group 1, 45 minutes and groups 2 & 3, 25 minutes. If you want to see how to use the equipment here is a link for the Nine-Hole peg test (9HPT) https://www.youtube.com/watch?v=U1lzIXWByTI and a link to tell you more about Etee https://www.youtube.com/watch?v=qkB02Al4sm4. Please note that you will only use the Etee hand controller, not the headset.

You will then be asked to perform activities over a 4- week period.

- Group 1 will use the Virtual Reality for 45 minutes a day, 4 days a week for 4 weeks.
- Group 2 will use the 9HPT for 45 minutes a day, 4 days a week for 4 weeks.
- Group 3 will continue with activities you have been prescribed by your medical practitioner. This group will help us see if anything we are testing has any real effect.

We will have a final 20-minute meeting to repeat the 9HPT. We will then ask you to post back the equipment. Groups 1 & 2 will be sent a 37-item questionnaire via email to determine how interesting and valuable their experience was. Group 1 will also fill out a 10-item questionnaire asking about their experience using the VR.

4. Expenses and payments

No expenses or payments will be made to you. All postage will be prepaid, and we will provide addressed packaging/envelopes. If you are unable to post the materials back, we can arrange collection from your home.

5. What are the possible disadvantages and risks of taking part?

Group 1 may experience a form of sickness from using VR, which is why we check if you are suitable for VR before starting the study**. However, if you feel sick, dizzy, or disoriented at any point while using VR, stop immediately, stay seated until any symptoms have eased. When you feel better please contact the researcher to inform them.**
You may experience fatigue or discomfort from the hand exercises, as you might following exercise. We advise you to take plenty of breaks, the 45 minutes can be spread out over the day to suit you. There is no reason for you to feel anxious or stressed, the object is to

try and note how long you have done the exercise if you finish earlier or run on longer. If you start feeling stressed, anxious, or uncomfortably fatigued, immediately stop the exercises and contact the researcher.

6. What are the possible benefits of taking part?

We cannot promise the study will help you directly, but the information we get from the study may help to increase the understanding of using VR as a home-based therapy. You may show some improvement in finger function.

7. Participant rights (data protection, confidentiality, and anonymity)

All information collected about you will be kept strictly confidential. Your data will be stored on an encrypted laptop, only the researchers will have access. After data is gathered all names linking a participant to their data will be destroyed, anonymising data. Signed consent forms will be held separately either in a password protected folder on an encrypted laptop, or in a locked cabinet at the university.

The data controller for this project is Dr Zeng at the University of South Wales. If you are concerned about how your personal data is being processed, please contact Compliance Manager, Mr Rhys Davies (rhys.davies@southwales.ac.uk). Details of your individual rights are available on the ICO website at: https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/

8. What will happen if I do not carry on with the study?

You have the right to withdraw at any time without reason, please tell us if you do, so we can arrange return of any equipment. If you withdraw before data collection has been completed all the information and data collected from you, to date, will be destroyed and your name will be removed from all study files. However, after data collection, as data will be anonymized, it will not be possible to identify and delete your data.

9. What will happen to the results of the research study?

The results of this study will form the basis of the researcher's (Bethany Strong) thesis and may also be published in scientific journals. You will not be identifiable in any publication.

10. Further information and contact details:

Thank you for taking the time to consider participating in this project. If you have any additional questions, please contact one of the research team using the information below.

Principal investigator	Bethany Strong	Bethany.Strong@southwales.ac.uk
Researcher	Biao Zeng	Biao.Zeng@southwales.ac.uk
Researcher	Peter McCarthy	Peter.McCarthy@southwales.ac.uk

If you have any issues with the study, please contact a member in the research team. If you are still not satisfied, please contact the University's Research Governance Officer – Jonathan Sinfield (jonathan.sinfield@southwales.ac.uk).