Research Participant Information Sheet

ReWiiRe: Exploring the use of adapted video gaming technology, for treatment of the arm after stroke

An Invitation to Participate

You are being invited to take part in a research study looking at the use of adapted video gaming technology in the recovery of arm movement following stroke. Before you decide whether to participate or not, it is important that you understand why the research is being done and what it will involve.

This information sheet provides an overview of the relevant information. Please read it carefully, discuss it with others if you wish and take time to decide whether or not you wish to take part. Please ask us if there is anything that is not clear or if you would like more information. We are also happy to go through this information with you in person or on the telephone and answer any questions that you may have.

What is the purpose of the study?

Most people who suffer a stroke, experience problems with arm movement and this lack of recovery has been linked to increased dependence on others and a reduced quality of life. Recently, in some therapy departments, video game technology has been used for rehabilitation following stroke. However, systems developed for use in hospitals and therapy departments are expensive and complicated to set up and use. While commercially available systems (such as the Nintendo Wii© and Microsoft Kinect©) have been found to be too difficult for many stroke survivors to use, as people often lack the range of movement, speed and dexterity required to use these systems following stroke.

In a previous study, undertaken by this research team, physiotherapists and stroke survivors used the commercially available Nintendo Wii© video gaming system as part of treatment. They then told us about what they liked and disliked about it, what they found difficult about using it and what improvements they would like to see. Engineers involved in the study then developed a new system, using adapted video game technology, to address the issues raised. This new system has the ability to be personalised (i.e. adapted to each person's individual needs after stroke) and is known as a **P**ersonalised **S**troke **T**herapy device (**PST**).

Before introducing a new therapy into practice is important to understand whether it is practical to use it, whether it is acceptable to use it from the service-user's viewpoint,

whether there are challenges associated with using it and whether it works. The planned study aims to examine these issues with the PST.

Why have I been invited to take part?

You have been invited to participate in this study as you had a stroke more than 12 weeks ago that has affected your arm movement and you have now finished all treatment for your arm. As some movement of the arm is required in order to use the PST, people who do not have any movement at all in their arm are not suitable for the present study. Due to attendance requirements, participants need to live within an hours travel.

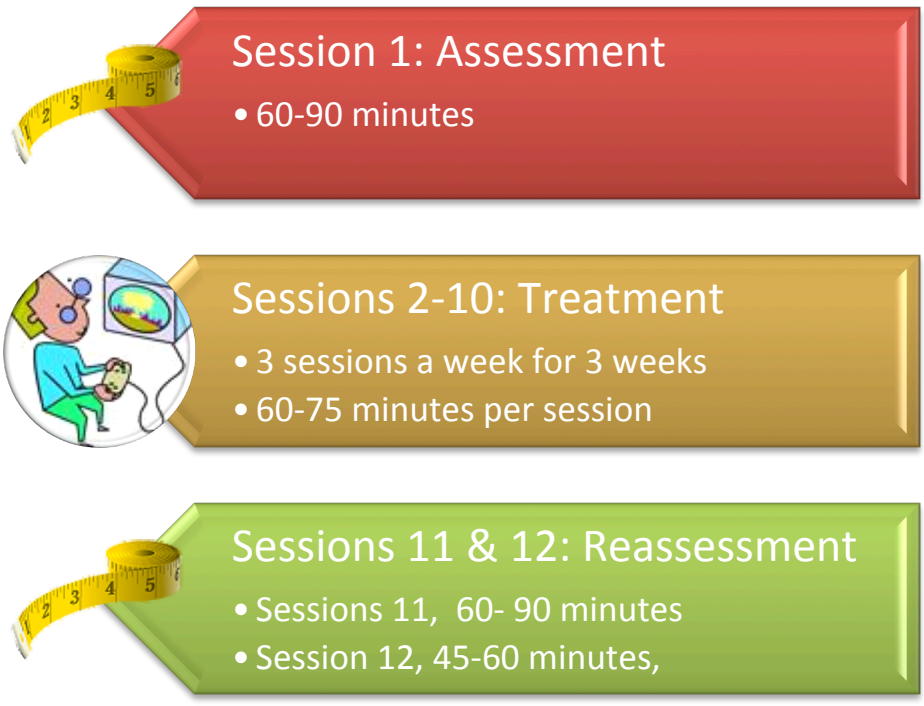
Do I have to take part?

As participation is entirely **voluntary**, it is up to you to decide whether or not to take part. If you decide to take part, you are still *free to withdraw at any time and without giving a reason. Refusal to participate or withdrawing from the study at any time will not affect any care or services you are receiving currently or may receive in the future.*

If you decide you would like to take part, you will be asked to sign two copies of a consent form. You will be given one copy of the consent form along with this information sheet to keep.

What will happen if I do take part?

You will be required to attend the university for 12 sessions lasting between 45 and 90 minutes each. The plan of what will happen is outlined in the diagram below and is discussed on the next page.



Baseline Assessment

If you decide that you would like to take part, you will be asked some questions by telephone, email or in person so we can start to assess your suitability to take part in the study. You will then be asked to attend the university to undergo some assessments to ensure that you are definitely suitable to take part in the study and to enable us to see how the stroke has affected you. You will also have the opportunity to discuss the study, ask any questions you may have and then decide whether you wish to take part or not. This first appointment will last between one and one and a half hours.

Treatment intervention

Following the first assessment appointment (described above), you will be required to attend the University for nine treatment sessions lasting for approximately 60-75 minutes each. These will be spread out over three days a week for three weeks. During this time you will play a game and practice activities using the PST with your arm affected by the stroke. In addition, the researcher will ask you a few questions about how you are and about your experience using the device.

Reassessment

The eleventh session will occur within three working days of you completing the treatment part of the study and involve you undergoing some of the same assessments you did in session 1 and having a short, audiotaped interview with the researcher about your experiences using the PST. It is anticipated that this session will last approximately 1 and a half hours. The twelfth and final session (lasting for about an hour), will occur four weeks after the eleventh session and again will involve you completing some of the same assessments as you did in the first session.

During each appointment you should wear loose fitting clothing on your upper body so you can freely move your arm. Refreshments will also be provided so you do not need to bring anything with you unless you would like to.

Is there anything I can't do during the study?

So we can make a fair assessment of the effect of the PST on your arm movement, it is important that you do not use video games that involve the arm affected by your stroke for the duration of the study and that the person who will perform most of the assessments of your arm does not know what

your initial scores were. Therefore it is important that you do not discuss this with them. You will be reminded about this at the start of each assessment session.

Where is the study taking place?

All assessments and treatment sessions will take place in a laboratory in the Mary Seacole Building at Brunel University. Free parking will be organised on request and travel expenses paid.

Who is doing the study?

The study is being carried out by physiotherapists and engineers from Brunel University, London. All physiotherapists are experienced in stroke rehabilitation.

What are the possible benefits of taking part?

The information provided by this study will enable researchers to examine whether it is possible, acceptable and safe to use the PST and whether it can help with arm recovery following stroke.

What are the possible disadvantages of taking part?

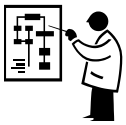
During its development, the PST has been used with several stroke survivors, none of whom suffered adverse effects. However, a number of risks remain including *arm pain and discomfort* as a result of using the device (these effects will be closely monitored and assessed throughout the study and you will be advised regarding appropriate management should this occur). In addition there is a risk of *motion sickness.* The risk is very low but occurrences will be monitored and if moderate to severe, you will be withdrawn from the study. There is a risk of *muscle stiffness* ("spasticity") associated with effort (as this is common with any effortful activity following stroke and usually resolves on rest, it is considered as low risk but will be monitored during each session). There is a very small risk of you tripping or *falling* when using the PST. One of the researchers will be watching throughout to minimise the risk should a fall look likely to happen. There is a theoretical risk of the PST inducing epilepsy *(*"a fit"). However this has not been reported in any previous studies using video gaming devices and recommendations for decreasing the risk will be adhered to. All researchers have experience with managing people suffering from epilepsy and are familiar with the NHS protocol for dealing with someone who is experiencing a fit. Finally there is a low risk that you may *feel upset* when exercising with the PST or when answering questions about your experience. Please let the researcher know if this is the case and she will signpost you to appropriate services for help. Also remember that you do not have to answer any questions that you do not want to and that you may withdraw from the study at any time without giving a reason and without this affecting any care you are or will receive in the future.

Will my taking part in this study be kept confidential?

Personal information collected during the research will be kept securely and will only be used to inform the findings of this study. All information and data about you will be treated as highly confidential. Direct quotes from the interview and other data and will be anonymised, meaning that it won't be possible to identify you in any part of the study that is written up or presented.

Although unlikely, should poor practice on behalf of health care staff become apparent, the research team have a duty to pass on this information in order to protect current and future patients.

What will happen to the results of the research study?



The information gained during this study will be used to write a PhD thesis. The results will also be presented to other people interested in the research and may be published in journals, and presented at conferences. You will be provided with a copy of the research findings should you wish to be.

Will I be paid to take part in the study?

This PhD study is unfunded and you will not be directly paid for taking part. However, travel costs will be reimbursed.

Who has reviewed the study?

Permission for this study has been given by The Research Ethics Committee of the School of Health Sciences and Social Care, Brunel University reference 14/06/PHD/02.

What if something goes wrong?

This study is insured by Brunel University. If you wish to have further information about this please contact a member of the research team.

What happens if I have a complaint?

Should you wish to make a complaint about any part of the study, please contact the chair of the ethics committee, Dr John Barker at ethics-shssc@brunel.ac.uk

Contact for further information

If you would like further information or have a question about this study or would like to take part, please contact:

Alyson Warland (lead researcher)	Alyson.warland@brunel.ac.uk	07854 066001 or 01895 268851
Dr Cherry Kilbride (PhD supervisor)	Cherry.kilbride@brunel.ac.uk	01895 268675

Thank you for taking the time to read this!