

# Participant Information Sheet



Study title: **A Game for Physiotherapeutic Rehabilitation for Stroke Survivors**

Locality: **Wellington**

Ethics approval number: **HDEC16CEN5**

Lead investigator: **Brian Robinson**

Contact phone number: **(04) 463 6155**

You are invited to take part in a study on a digital game system on the recovery process from stroke. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## WHAT IS THE PURPOSE OF THE STUDY?

This study is to develop computer controllers and computer games that can be used by people who are recovering from stroke. This is for rehabilitation that they can carry out by themselves at home.

We want to know how you find using the computer, the controller and the game. Our aim is that these will be easy to use and understand as well as rewarding for you. It is also important that the movements made when using the games will help with stroke rehabilitation.

These devices and games are developed by students as a requirement for a Masters degree. This research is funded by the School of Design at Victoria University of Wellington. Any other questions you have can be answered by Dr. Brian Robinson (463 6155)

This research has been approved by the Health and Disability Ethics Committee.

## WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We asked you to take part in this research because you have experienced a stroke and may have limited use of one of your legs.

The research study will take place either at a Stroke Club or in your home.

If the research study takes place in your home, two research students will come. They will bring mobile telephones with them so that they can contact their research supervisors.

We will ask some questions about you such as how old you are, your ethnic background, how long ago you had the stroke and how the stroke affects you now.

We will show you a computer, a computer controller and a game.

You will be asked to use the computer and the control device to play a computer game.

You can play this game for as long as you like and can tell us when you want to stop.

We will take a video and photographs of you using this computer controller and game. This is to make sure that using the controls and the game in ways that will be useful for stroke recovery and not cause harm. Stroke rehabilitation physiotherapists will review these recordings. We will keep the video and photographs securely in the University. Because other researchers will be interested in our research we may show the photographs or a video of you. Your involvement in the study will only be known by the researchers. All photographs and videos will be taken using cameras belonging to the School of Design. The images and videos will be taken off these cameras and immediately after this session and then kept secure in the University computer system.

If we do use photographs or videos of you for presenting our research we will not show any part of you, such as your face, that can tell other people that you have taken part. If we take pictures in your home, we will also make sure that we do not show anything that identifies your house or that you took part. We will do this by blurring parts of the images and videos. We will ask you for your thoughts on using the computer control and game. We will record what you say. If you tell us something useful that we quote, we will not use your name with what you say”.

Your participation requires your concentration using the game or device. We realize that this can be tiring for you so we ask you can tell that you are wanting to rest or to stop the session. You may be invited to take part again if you would like to help us test changes.

## WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We know that people who have had stroke cannot access stroke rehabilitation therapy regularly. They have to travel to clinics or hospital. We also know that rehabilitation is more effective when it is carried out for several hours throughout day, every day.

This study is to support people who have had a stroke to provide stroke rehabilitation therapy in their home. This can be by themselves or with the help of carer support or family members.

We want to find out whether this device or game may be useful in stroke rehabilitation. This research is finding out whether you can use it and what you think of it.

This does not replace any other therapy you may be receiving. We are not using the device and game as part of your therapy at this stage. We want to find out whether this might be usable as a therapeutic device.

While you are using the computer and playing the game you will be required to perform specific physiotherapy exercises from a standing position. If you are unable to do this, there is a seated equivalent that can be performed.

## WHO PAYS FOR THE STUDY?

This study is funded by Victoria University of Wellington and the School of Design through medical technology research grants from the Ministry of Business, Innovation and Employment.

You will not incur any costs by taking part and we will travel to you.

## WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

## WHAT ARE MY RIGHTS?

You are volunteering to take part. You do not have to take part in this study and you can withdraw at anytime.

We can show you the video recording and photographs of you we have collected. We can also give you a copy of what we have recorded you saying to us about using the computer device and game.

It is unlikely that participating will affect your health but if it does, we will contact you immediately.

We will not identify you in any of the students work or presentations of the work.

## WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

After you have taken part and change your mind about being involved, please contact the researcher (the design student) or the lead investigators (Brian Robinson, in the first instance, or Edgar Rodriguez) and any data, information and images associated with your participation will be destroyed.

We will securely store the information and data you have provided for five (5) years and it will then be destroyed.

We can present the findings of this study at stroke clubs within a year of conducting the study.

We can also send you a summary of the student's thesis describing the outcome of the study.

We may also present this study with other similar studies we are conducting at conferences or in books or journals.

## WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Brian Robinson, Senior Lecturer, Graduate School of Nursing, Midwifery & Health,  
Victoria University of Wellington.  
Work phone: (04) 934 9321  
brian.robinson@vuw.ac.nz

24 Hour contact numbers:

Dr Robinson: 029 776 9321

If you cannot contact Dr Robinson, please contact

Associate Professor Edgar Rodriguez: 027 563 6544

If you have other questions, concerns or complaints and wish to contact a Māori support person, you can contact:

Katherine Reweti- Russell, Research Advisory Group – Māori, CCDHB  
Work phone: (04) 806 2524

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: advocacy@hdc.org.nz

For Maori health support please contact your health provider and they will refer you to the representative Maori health support group.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS  
Email: hdec@moh.govt.nz

# Consent Form



**If you need an INTERPRETER, please tell us.**  
*If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet*

## Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes <input type="checkbox"/>
I have been given sufficient time to consider whether or not to participate in this study.	Yes <input type="checkbox"/>
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes <input type="checkbox"/>
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes <input type="checkbox"/>
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes <input type="checkbox"/>
I consent to the research staff collecting and processing my information, including information about my health.	Yes <input type="checkbox"/>
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes <input type="checkbox"/>
I consent to the research staff taking pictures or video recordings of me and I understand that if used in presentations, these will be altered so that I or my involvement cannot be identified.	Yes <input type="checkbox"/>
I understand the compensation provisions in case of injury during the study.	Yes <input type="checkbox"/>
I know who to contact if I have any questions about the study in general.	Yes <input type="checkbox"/>
I understand my responsibilities as a study participant.	Yes <input type="checkbox"/>
I wish to receive a summary of the results from the study.	Yes <input type="checkbox"/> No <input type="checkbox"/>

**Declaration by participant:**

I hereby consent to take part in this study.

Participant's name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: Scott Brebner Will Duncan \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_