

****

College of Health and Life Sciences

Department of Clinical Sciences

**PARTICIPANT INFORMATION SHEET**

**The RHOMBUS Study:**

**Rehabilitation via HOMe Based gaming exercise for the Upper-limb post Stroke**

We would like to invite you to take part in a research study. Whether or not you wish to take part is entirely up to you. Before you decide it is important for you to understand why the research is being done and what it will involve. To help you decide please take time to read the following information carefully. Feel free to talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information

**Please take time to decide whether you wish to take part**

You are being invited to take part in a research study looking at the use of a new gaming device called the Gameball (right) which has been designed by Neurofenix specifically for rehabilitation of the arm following stroke.

**Part 1** of this leaflet tells you the purpose of this research and what will happen to you if you decide to take part

**Part 2** gives you more detailed information about the conduct of the research

**Part 1 - Overview of the Study**

**The Gameball**

**What is the purpose of the study?**

Before introducing a new device into therapy it is important to understand whether it is safe, enjoyable and easy to use from a stroke survivor’s viewpoint and whether there are challenges associated with using it. The planned study aims to examine these issues when using the Gameball at home to help exercise the arm and hand following stroke.

**Why have I been invited to participate?**

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 are currently not receiving treatment for your affected arm.

**Who can take part in the study?**

Men and women who had a stroke can take part in the study if they:

* Had a stroke at least 12 weeks ago that affected arm movement
* Still have problems moving their arm

You are **not eligible** to take part in the study if you:

* Are still having regular treatment for your affected arm
* Have no movement in your arm and hand (including your shoulder) at all
* Have pain in the arm at rest
* Have epilepsy triggered by rapid changes in light
* Are unable to understand or communicate in English
* Have had a stroke that has affected both sides of your body
* Are unable to sit independently for 5 minutes before requiring rest
* Have visual problems that cannot be corrected by glasses
* Have an unstable medical condition

**Please let the researcher know if you have pain in the arm on movement**

**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, we will ask you to sign a consent form. If you decide to take part you are still free to change your mind and withdraw at any time and without giving a reason.

**What will happen to me if I take part?**

Screening: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 take part in some assessments, performed by a researcher on a visit to your home, to ensure that you are suitable to take part in the study and to enable us to see how the stroke has affected you. Once we have confirmed your suitability to take part, you will have a further opportunity to discuss the study, ask more questions and then decide whether you wish to take part or not.

**What will happen to me if I take part? (continued)**

Consent: 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.

First assessment: After consenting to participate, you will be asked to take part in further physical assessments and to complete a range of questionnaires. This may take up to an (1) hour and includes various measures of arm and hand function and quality of life. You can have as many breaks as you like during this time.

Training session: At a follow-up appointment a week later, a researcher will bring a Gameball to your home and show you how to use it and play the games. You will be given an instruction booklet and you will be able to ask questions to the researcher at any time during the session. After this appointment, you will be asked to slowly increase the time you spend playing the Gameball for the next week. At the end of that week you will be asked to play the Gameball for approx. 30 - 45 mins a day for the next six weeks (this recommendation may vary according to how tired or energetic you may feel).

Follow-up assessments: In order to assess any changes after using the Gameball device you will be asked to take part in another assessment and to complete a range of questionnaires at the end of the six weeks of Gameball use and then a final assessment four weeks later. The researcher will visit your home for these assessments and they will take about two (2) hours to complete.

Request to film an assessment: In order to assess any changes in function after using the Gameball device, we would like to use a video camera to record information regarding how you move during a certain assessment. ***However, you have the option to not be filmed if you prefer.*** While cameras will be placed to record body and arm movements, it is possible that the camera may accidently record your face. Should this occur, **computer technology will be used to blur your face** so that it will not be possible to recognise you when we play back the video recordings**. If you do not wish to have your face blurred, you have the option to agree to the recording of your face on the consent form.** The recordings will then be assessed by a second research assistant.

**What will happen to me if I take part? (continued)**

Interview: You may be invited to an interview with a researcher to further discuss your experience using the device and taking part in this research.

Request to not play other video games: As this study is designed to look at the changes from using the Gameball, you will be asked to only use the Gameball and not use any other video gaming technology involving your affected arm for the duration of the study (from the first training session to the last follow up session or 11 weeks). You may however continue to use your unaffected arm to use a computer and other gaming technology for the duration of the intervention.

**What are the possible disadvantages and risks of taking part?**

During its development, the Gameball has been used with many stroke survivors, none of whom suffered harmful side-effects. However, a number of small 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 and usually resolves on rest, but occurrences will be monitored and if moderate to severe, you will be withdrawn from the study. There is a low risk of *headache* and *eye strain* when using the display equipment of the tablet. The tablet brightness and contrast can be changed to improve your comfort when using the device. Eye strain and headaches usually resolve on rest, however if persistent or consistently reoccurring, please let the research team know and you will be monitored and potentially 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 you will be asked to monitor this during each session). There is a very low risk of the Gameball inducing *epilepsy* *(*“a fit”). However, this has not been reported in any previous studies using video gaming devices. Finally, there is a low risk that you may *feel upset* when exercising with the Gameball or when answering questions about your experience. Please let the researcher know if this is the case and s/he 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.

**What are the possible benefits of taking part?**

As we are still testing the Gameball, we cannot promise that taking part will benefit you but if you do take part in the study you will have seven weeks of access to the Gameball platform: a hand controller or arm bands that allow arm training through rehabilitation games displayed on a tablet. You will also have access to the results of the assessments if you wish to have them for your records.

**What will happen if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it.

Please contact a research member if you have any clinical or technical issues during the study. You can find their contact information at the end of this form. If you have any complaints or questions about how the research has been performed, please contact Professor Christina Victor, Chair College of Health and Life Sciences Research Ethics Committee Christina.victor@brunel.ac.uk.

**Part 2 – Conduct of the Research**

**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 and will be maintained consistent with the Data Protection Act 1998. This information will not be shared with medical services and therefore please tell your GP (and us) about any changes in your condition. All data 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.

There is one important exception to the guarantee of confidentiality. If you tell us something that suggests that you or others are being placed at risk of significant harm, we are obliged to pass this information on. We will talk to you about the procedure involved before the information is shared.

**Will my taking part in this study be kept confidential? (continued)**

Data produced by the research team will be anonymised and shared with Neurofenix, the creators of the Gameball, so they can better understand the more technical data generated by the Gameball device. This information is being shared to improve future designs of the Gameball device and game platform.

Data generated by the Gameball device includes the number of repetitions of Gameball movements, time spent exercising, range of Gameball movements, as well as other technical data related to the Gameball device. This information will be gathered by the laptop via Bluetooth and then securely sent automatically via email to Neurofenix.Although no identifying information will be included, these emails are still considered sensitive data and will use a Data Privacy Protocol, a way of ensuring your data is protected when it is sent through the internet. This protocol has been created with the advice of the Information Commissioners Office. Neurofenix is fully compliant with the upcoming EU General Data Protection Regulation.

**What would happen if I don’t want to continue with the study?**

You can withdraw from the study at any time and without giving a reason. If you choose to withdraw you would be asked which type of withdrawal you would prefer – you can choose between leaving the study and allowing the anonymous information already given to be used by the study team OR leaving the study and asking for the anonymous information already given by you to be destroyed. If you withdraw from the study this will not affect your future participation in your stroke group in any way.

**What will happen to the results of the research study?**

The information provided by this study will enable researchers to examine whether it is possible, safe, enjoyable and easy to use the Gameball at home for hand and arm rehabilitation following stroke. 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.

All information from the study will be securely stored for five years after the study has ended and then be destroyed.

**Will I be paid for taking part in the study?**

Unfortunately, you will not be directly paid for taking part in this study. However a small gift voucher will be offered as a token of appreciation.

If you do not wish to take part in the study, we would still like you to consider completing a short questionnaire to help us identify reasons why people do not want to take part in the study as this will help us design better studies in the future. Those completing the questionnaire will be offered a chance to win a gift voucher as a token of appreciation; there will be a prize draw at the end of the study recruitment phase.

**Who is organising and funding the research?**

The study is being organised by researchers from Brunel University London in collaboration with engineers and designers from the Neurofenix company who make the Gameball. Funding for the study is provided by Innovate UK.

**What are the indemnity arrangements?**

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

**Who has reviewed the study?**

This study has been reviewed by the Research Ethics Committee of the Department of Clinical Sciences, College of Health and Life Sciences.

*Brunel University is committed to compliance with the Universities UK* [*Research Integrity Concordat*](http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf)*. You are entitled to expect the highest level of integrity from our researchers during the course of their research.*

**Contact details for further information and for raising concerns are**

**on the next page**

**Contact for further information**

If you would like any further details about taking part in this study, would like to ask us any questions, or would like to express your interest in taking part then please do not hesitate to contact a member of the Rhombus team. You can call or text the team on 077 8022 5384 or email Rhombus@brunel.ac.uk

**Contact for further information and complaints**

|  |  |  |
| --- | --- | --- |
| Rhombus Members | Rhombus@brunel.ac.uk  | 077 8022 5384 |
| Daniel Scott | Daniel.scott@brunel.ac.uk  | 01895 265592 |
| Thomas Butcher | Thomas.butcher@brunel.ac.uk  | 01895 266925 |
| Dr Cherry Kilbride | Cherry.kilbride@brunel.ac.uk  | 01895 268675 |

**For complaints and questions about the conduct of the research**

Professor Christina Victor, Chair College of Health and Life Sciences Research Ethics Committee Christina.victor@brunel.ac.uk

**Thank you for taking the time to read this!**