

## **1. Study Title.**

### **Testing a Novel Game-Based Protocol to Enhance Hand Function after Stroke**

## **2. Invitation paragraph.**

You are being invited to take part in a research study. Before you decide it is important 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 others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

## **3. What is the purpose of the study?**

After a stroke, many people find that their hand on the affected side becomes weaker and less dextrous. This is because the stroke has damaged pathways communicating from the brain to the spinal cord. We have developed a new approach to strengthen these pathways, by combining rhythmic movements with electrical stimulation of a nerve in the arm. In this study, we will test whether this approach can improve hand function after stroke.

## **4. Why have I been chosen?**

We have asked you to help us today because you have had a stroke more than 6 months ago. You must be over the age of 18 to participate; there is no upper age limit. Because the study involves electrical stimulation, if you have any implanted device (e.g. a pacemaker), you should decline to participate in this study; you do not need to tell us the reason for your decision.

## **5. Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

## **6. What will happen to me if I take part?**

You will make three visits to our laboratory in the Henry Wellcome building at Newcastle University for 1-2 hours. The three visits will be over an eight week period (four weeks between visits).

On the first visit, we will ask you for details of your stroke, your age and sex, and of any medications that you are currently taking. We will record these for our records.

On each visit, we will perform some tests which measure how well you can use your affected hand, or how well the pathways from brain to spinal cord are working. Some of these test whether you can complete certain tasks, or how quickly or well you can do them. Others will measure your muscle activity using electrodes stuck to your skin, and the responses to stimuli given either to your head or to your arm. One of the tests involves responding as quickly as you can to a light flash; sometimes this is accompanied by a loud sound. We will explain everything as we go along; please feel free to ask questions.

In between either your first and second, or second and third visit, we will give you a device and mobile phone game to allow you to practice repetitive movements paired with electrical stimulation at home. You will need to spend around **30 minutes each day** playing this game.

Please do not agree to participate in the study if you are not able to give this amount of daily commitment.

Before issuing you with the device and phone game, we will ask you for contact details of family and friends who are interested in your recovery. If you do not play the game by an agreed time each day, the game will automatically message these people, and encourage them to check in with you. This is to help you keep motivated and improve the changes of recovery. You can opt out of this if you wish.

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

The methods which we will use in this study are straightforward, and safe. Many are routinely used by doctors for diagnosing and treating their patients. None of the methods to be used will cause any lasting harm.

## **8. What are the possible benefits of taking part?**

It is possible that you may gain improved hand function from taking part in this study, but there is no guarantee that this will be the case. Whatever the results, we will have learnt more about this protocol, which could lead to improved therapies for hand function after stroke in future.

## **9. What if something goes wrong?**

This is very unlikely; we have regularly carried out similar studies in our laboratories for many years without problems. However, it may be helpful to know that if you were harmed by taking part in this research project, compensation may be available under an insurance policy held by the Newcastle University. Regardless of this, if you wish to complain, or have any concerns or comments about any aspect of the way you have been approached or treated during the course of this study, you should in the first instance contact Prof. F. Sargent, Director of the Institute of Biosciences, University of Newcastle, The Medical School, Framlington Place, Newcastle, NE2 4HH.

## **10. Will my participation in this study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential. Your personal details will be recorded only on the consent form; these will be stored securely in the laboratory for ten years after the study has been completed, and then destroyed. All electronic files relating to the study will be stored under an anonymised identifier. Any information about your participation in the study which leaves the laboratory will similarly not include your personal details, so that you cannot be recognised from it. Our use of your data complies with the General Data Protection Regulations.

You will be given a copy of this information sheet to take away with you, and may wish to show it to your GP if you want to discuss your participation in the study with him or her.

## **11. What will happen to the results of the study?**

The results of this study will be published in scientific journals. If you would be interested in seeing a copy of the final paper, please let us know and we will send you one when it is published.

## **12. Who is organising and funding the research?**

These experiments are supported by internal funds within Newcastle University.

## **13. Who has reviewed the study?**

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This Committee includes members who are internal to the Faculty. This study was reviewed by members of the Committee, who must provide impartial advice and avoid significant conflicts of interests..

#### **14. Contact for further information**

This sheet provides basic information about the experiment. We will explain more as we go along; please feel free to ask questions. The head of the laboratory in which these experiments are carried out is Prof. Stuart Baker. Please contact Prof. Baker (0191 208 8206; email [stuart.baker@ncl.ac.uk](mailto:stuart.baker@ncl.ac.uk); postal address Henry Wellcome Building, Medical School, Framlington Place, Newcastle upon Tyne, NE2 4HH)) if you have any queries about the study after you leave today.

Thank you for giving your time to this study.

*“Stroke Tapping Game” Volunteer information sheet version 2.0 dated 5<sup>th</sup> December 2024.*

Henry Wellcome Building,  
Newcastle University,  
Faculty of Medical Sciences  
Framlington Place,  
Newcastle upon Tyne, NE2 4HH

Study Identification: Stroke Tapping Game  
Subject Identifier for this Experiment:

## CONSENT FORM

Title of Project: Testing a Novel Game-Based Protocol to Enhance Hand Function after  
Stroke

Name of Researcher: Stuart Baker

Please initial box

1. I confirm that I have read and understand the information sheet dated 5<sup>th</sup> December 2024 (version 2.0) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I confirm that I have no implanted medical devices (these could be adversely affected by the stimulation used in this study).
4. I consent to the processing of my personal information (name, date of birth, sex, details of stroke and medications) for the purposes of this research study, as described in the information sheet dated 5<sup>th</sup> December 2024. I understand that my anonymised research data may be published as a report or paper, and I consent to my anonymised research data being stored and used by others for future research.
5. I agree to take part in the above study.

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Name of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from researcher)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

One copy for volunteer; one for researcher