

**LONDON’S GLOBAL UNIVERSITY**

**SOBELL DEPARTMENT OF MOTOR NEUROSCIENCE AND MOVEMENT DISORDERS**

**UCL INSTITUTE OF NEUROLOGY**

**THE NATIONAL HOSPITAL FOR NEUROLOGY AND NEUROSURGERY**

**QUEEN SQUARE**

**INFORMATION FOR STROKE SURVIVOR VOLUNTEERS**

**MOvement Control After Stroke (MOCAS) Study**

**Scientific Title of Research:** Does intensive rehabilitation improve upper limb motor control processes and reduce chronic motor impairment after stroke?

**Name of Chief Investigator:** Prof Nick Ward, Sobell Department of Motor Neuroscience and Movement Disorders

**Educational Project:** This research will be conducted in part fulfilment of a PhD

**UCL Project ID Number:** 17/0209

**IRAS Project ID Number:** 222832

**REC Reference:** 17/LO/1466, this study has been reviewed and approved by the London – Camden and Kings Cross Research Ethics Committee.

*September 2017, Version 1.1*

We would like to invite you to take part in our research study. Before you decide whether to take part, it is important for you to understand why the research is being carried out and what it will involve for you.

Please read and consider this information carefully. You may wish to discuss it with others. If there is anything you do not understand, or if you would like more information, please ask us. Take time to decide whether you would like to take part.

Section 1 contains information about the MOCAS study and what will happen if you decide to take part. Section 2 contains information about the conduct of the study, such as issues of confidentiality. You should read both sections before you make a decision.

**SECTION 1**

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

Your stroke has left you with lasting damage to the part of your brain that controls movement in your upper limb (arm and hand) so that you can no longer use it as you could before the stroke. We know that intensive rehabilitation helps people regain movement in their affected arm in the first few months after a stroke, but the current consensus is that little, if any, further improvement is possible in later months and years.

However, recent clinical and scientific studies have shown us that an intensive upper limb rehabilitation programme may also help reduce chronic arm and hand weakness and disability for people whose stroke occurred at least 3 months earlier. It is important that we understand how this is happening so that we can improve our knowledge of how people recover from a stroke and provide the best possible treatment at all stages of the recovery process to ensure the best possible outcomes for all stroke survivors.

In this study, we will accurately measure and assess your ability to move and control your affected arm and perform simple tests of your ability to adapt your movements to changing conditions and learn simple motor skills. This will help us to understand how movement in chronic stroke patients has been affected and how it might be improved with rehabilitation. There may be no direct benefit to you from taking part, but the information we gain will improve our understanding of how people can continue to recover from their stroke in later months and years and may guide future development of treatment and services for all stroke survivors.

**Why have I been invited?**

We are inviting you because your stroke happened at least 3 months ago and has caused lasting problems with movement in one of your arms or hands. We hope to include the following groups of people in this study:

* 50 participants who suffered a stroke at least 3 months ago, who have lasting problems with movement in one arm or hand, and who will be attending the upper limb rehabilitation programme at the National Hospital for Neurology and Neurosurgery under the care of Dr Nick Ward (consultant neurologist)
* **25 participants (like you) who suffered a stroke at least 3 months ago and are no longer under the care of a stroke team, but who have lasting problems with movement in one arm or hand, and will NOT be attending the upper limb rehabilitation programme and have never had any intensive rehabilitation for the affected arm or hand**
* 25 healthy participants who have never suffered a stroke and have no problems with movement in their arms or hands (to provide a comparison group for those affected by stroke)

**Do I have to take part?**

No. Your participation in this research study is voluntary. You will be given plenty of time to think about whether you would like to take part and a researcher will then contact you to ask if you would like to participate. If you decide not to take part, you will not be asked to explain your reasons for this and you will not be contacted again about this study

**What happens if I do decide to take part?**

If you decide to take part, a researcher will arrange to meet you at the Sobell Department of Motor Neuroscience and Movement Disorders at a time that is convenient for you. The researcher will explain the details of the study to you again, and ask you if you have any questions. You will be asked to complete a brief medical screening questionnaire to confirm that you are eligible and it is safe for you to participate in the research. You will then be asked to sign a consent form confirming your agreement to participate. You will be given a copy of the consent form to keep and a copy will be kept in the research office. You should also keep this information sheet to refer to throughout the study. Your participation in this study remains voluntary and you may still withdraw at any time without having to explain your reasons for doing so. In the event of your withdrawal, we would not use any data we may already have collected from you in this study.

**What is involved in the MOCAS study?**

**Schedule**

If you decide to take part in this study, you will attend 2 separate testing sessions at the Institute of Neurology in Queen Square as follows:

1. **First session (baseline) approx. min.**
2. **Second session 3-weeks after the baseline session approx. 45 min.**

*\*\*You must be able to complete BOTH testing sessions to take part in the study\*\**

**Motor control research laboratory**

At each session, a research doctor will take you to the motor control research laboratory in the Sobell Department of Motor Neuroscience and Movement Disorders. We will take some simple clinical measurements of the size, strength and range of motion of your arms. Then we will ask you to perform some simple reaching movements and behavioural tasks that allow us to make accurate measurements and assessments of various motor control processes occurring in the motor pathways between your brain and your upper limb. There will be plenty of time for you to familiarise yourself with the laboratory, the equipment and the tasks. The session will last no longer than 60 minutes in total and there will be regular breaks throughout. Refreshments will be available and there are fully accessible toilet facilities just outside the laboratory. Finally, we will ask you to complete a very short questionnaire about your levels of attention and concentration, fatigue, and the severity of any pain or stiffness you may have. This is because these factors may also affect your motor control processes.

**Robotic arm reaching task**

You will sit in a high-backed chair with your forehead resting on a headrest in front of a workstation housing a robot controlled arm (pictured). We will ask you to place the forearm of your affected arm in a specially moulded cast, which fully supports the weight of your arm. Straps will keep your arm in the correct position. You will hold or place your hand around the large cylindrical handle of the robotic arm. If this is too difficult, we will use a purpose made wrist-extension support to help you. Moving the handle of the robotic arm controls a cursor displayed on a horizontal computer screen, positioned so that you cannot see what your arm is doing. We will ask you to make repeated simple reaching movements to move the cursor between selected targets and at different speeds. You will perform several trials in blocks, separated by short rest periods.

The robot makes precise measurements of your reaching movements, such as the position of the arm, the speed of the movement, or the force with which you move the arm. We will analyse this data once you have finished testing to learn about the motor control of your arm. We will also test your ability to adapt to changing conditions by asking the robot to interfere with the movements you make towards the targets. You will probably notice this by feeling that the movement becomes a little more difficult, or that the screen cursor does not seem to move the way it did before. During this section of the movement testing, we may also record your muscle activity using sticky pads and wires that are attached to your skin.

Testing motor control behaviour with the robot-controlled arm is a well-established, non-invasive method that will not cause you any harm. If you do become tired, you will be able to ask for an additional rest period.

**What are the risks and benefits?**

The methods used in this study are well-established procedures that are non-invasive and harmless and carry no known risks. Our labs have conducted these types of experiments for previous studies, including studies with people who have suffered a stroke and with other patient groups. Although your participation in this research study will have no direct benefit for you, the results of the study may be valuable for future research activities, clinical treatment, and service provision for stroke survivors.

**Expenses and payments**

You will be reimbursed for your time and possible travel expenses. This will be £20 per visit, which is the standard remuneration for research participants at the Institute of Neurology.

**SECTION 2**

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

Yes. All the information about your participation in this study will be kept strictly confidential. You will be assigned a study code so that your data will be made anonymous at the point of data collection and it will not be possible to identify you from your results. Any information or data about you that is made visible to anyone other than the research team or your treating clinical team will have all your personal identifiable information removed so that it will not be possible to identify you. If the overall results of this study are published in scientific journals, all personal data will remain confidential and no data relating to individual participants will be published.

**What happens to the information collected in this study?**

The UCL Institute of Neurology and The National Hospital for Neurology and Neurosurgery are the “data controllers” for the MOCAS study and the organisations responsible for collecting, storing, handling and processing the information collected. Prof Nick Ward is the Chief Investigator for this study and he is responsible for the safety and security of the study information. No other organisations may access the study information without his permission. If he were to grant permission, the data would remain in anonymous coded format and participants would not be identifiable. After the research study has ended, anonymous data will be stored by UCL for 20 years in accordance with the UCL Records Management Policy and the Data Protection Act, 1998.

**What will happen if the findings affect me personally?**

The tests used in the motor control research laboratory section of this study are currently research tools only and of uncertain clinical significance. We do not expect them to affect you personally. If you do feel affected in any way by your participation in the study, you should discuss this with one of the research doctors.

**Will I know the results of the study?**

Yes. Once the study is complete and a summary report of the main findings has been prepared, you will be informed by email or post and provided with a copy. Following publication of the results in a peer-reviewed journal, you will also be able to receive a copy of the published journal article if you wish.

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

This project is being organised by the UCL Institute of Neurology in conjunction with the National Hospital for Neurology and Neurosurgery, University College Hospital London NHS Foundation Trust and is funded by The Wellington Hospital.

**Who do I contact if I have a concern about the study or I wish to complain?**

If you have comments or complaints about your participation in this research study, please contact your study doctor in the first instance. If you are not satisfied with the response, please contact the chief investigator, Dr Nick Ward (contact details listed at bottom of this information sheet).

If you remain unhappy or wish to make a formal complaint, you may contact the UCLH Patient advice and liaison service (PALS). PALS can be accessed via pals@uclh.nhs.uk where an electronic contact form is available, by telephone (020 3448 3237) or by visiting the PALS office at the National Hospital for Neurology and Neurosurgery (NHNN) site between 9am and 4 pm, Monday to Friday (except public holidays). The PALS office is located on the ground floor of the Royal London Hospital for Integrated Medicine building, near the pharmacy and library:

NHNN PALS

Royal London Hospital for Integrated Medicine (RLHIM)

60 Great Ormond Street

London

WC1N 3HR

020 3448 3237

There is a dedicated voicemail service when an officer is not available or the office is closed and the PALS team endeavour to answer all voice and email messages within 24 hours, or by the next working day.

In the unlikely event that you experience harm through your participation in research, UCL has arrangements in place to provide for compensation.

**Who has reviewed this study?**

All research conducted at UCL is examined by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. The MOCAS study has been reviewed by and received ethics clearance through the London – Camden and Kings Cross Research Ethics Committee.

**Who can I contact for further information about this study?**

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| **Dr Angelo Dawson MBBS BSc MRCP****Mobile 07984069495****ang.dawson@ucl.ac.uk**Sobell Department of Motor Neuroscience & Movement Disorders UCL Institute of Neurology Box 146, 4th Floor33 Queen Square London WC1N 3BG  |

**Thank you for taking the time to read this information sheet**