Date: 19/05/2020 **IRAS Project ID: 266827** **Version: 2.0**

A Participant Information Sheet

1. Study title

Post-stroke Hand Rehabilitation with Brain-Robot Interface

2. Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you understand what the research is for and what you will be asked to do. Please read the following information and do not hesitate to ask any questions about anything that might not be clear to you. We thank you for taking the time to consider this invitation.

3. What is the purpose of the study?

Over 20M people suffer from stroke annually world-wide and up to 77% of stroke survivors may have weakness in their arm and will have problems doing day to day activities. Unfortunately, despite undergoing a range of therapeutic treatments, many people with weakness in their arm and hand fail to make full functional recovery, adversely affecting their quality of life and employability. In recent years it has been found that much improved recovery can be gained if such people perform intensive active physical practice in conjunction with imagination of activities of daily living. Although physical practice can be performed with the help of a therapist, it is expensive and limited; and dependence on the therapist may lead to performing exercises inattentively with little focus, called "passive practice". To this end, it is proposed to investigate development of a lightweight neuro-rehabilitation system for people with stroke that facilitates intensive active physical as well as mental practice with the help of a robotic exoskeleton and a visual feedback based on brain signals from a non-invasive brain-computer interface (BCI).

The neuro-rehabilitation system involves a robotic hand exoskeleton that is worn by the study participants and is controlled through brain signals measured by a BCI. The BCI obtains brain signals from Electroencephalography (EEG) or Magnetoencephalography (MEG) system. So when someone thinks about moving their arm, specific signals are activated in the brain that control this movement, and this is measured by the BCI system. At the same time, our system will also measure muscle activity in the arm in which movement is being thought about. The exoskeleton is controlled in such a way that it applies additional force only after the user has tried his/her best to accomplish the experimental task but could not complete. This mode of control is called the 'assist-as-needed' mode. Additionally, the person's brain signals are displayed on the computer screen, so giving visual feedback, which can help someone to perform the physical as well as mental practice with focused attention, as the feedback identifies if the user is correctly performing the practice.

a) What is a robotic hand exoskeleton?

A robotic hand exoskeleton is a wearable mobile system that facilitates finger movements in people with hand impairments. As shown in Fig. 1, our hand exoskeleton involves joints and links mechanisms of a combined index & middle fingers and thumb. The exoskeleton can be controlled by imagining the movement of fingers using a BCI.

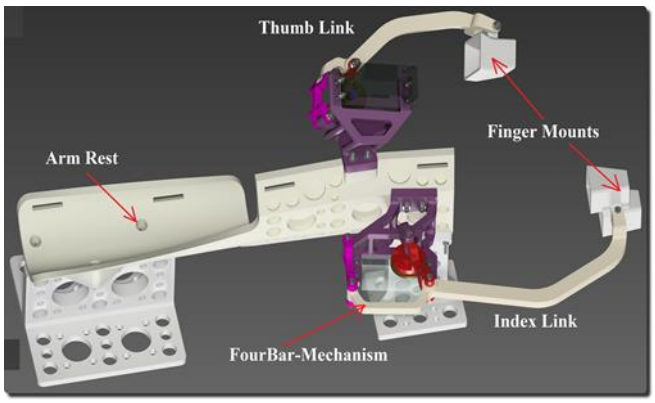

Fig. 1: The hand exoskeleton which includes an arm rest, and finger mounts at the end of thumb and index links for the placement of user's fingertips.

b) What is MEG?

Magnetoencephalography (MEG) is a modern non-invasive technique for measuring magnetic fields generated by the brain in the space above the scalp. It is a completely safe and non-invasive neural imaging technique which records the miniscule magnetic fields produced by brain activity using delicate sensors. MEG is housed in a magnetic shielded room (MSR) for reducing noise from the surrounding environment. It allows very fast measurement of ongoing brain activity. As seen in Fig. 2, study participants will be seated on a comfortable chair with their head placed inside the helmet of MEG sensors that are able to detect extremely small magnetic signals produced by the brain. Magnetising metallic objects are not allowed in the shielded room so as to reduce noise in the recorded signals. The research team will ensure that participants do not carry any metallic object in the shielded room.

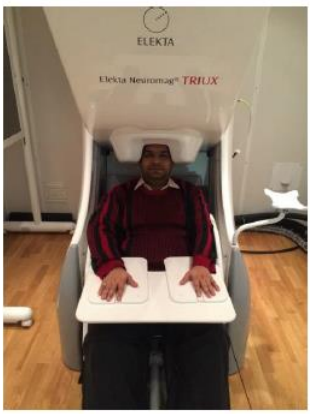

Fig. 2: A participant seated in the MEG scanner housed in an MSR.

4. Why have I been chosen?

You have been approached to take part in this study as an adult volunteer with hand impairments and/or having special interest in helping move forward the research. Also, you are eligible to participate in this study only if:

- *You are post-stroke volunteers, in the age group of 18-80 years and have normal or corrected to normal vision.*
- *You had your stroke six months to two years ago.*
- *You can get in and out of a low seat unassisted,*
- *You do not have any metal or active implants in your body (excluding dental fillings or crowns),*
- *You can remove all body piercings,*
- *You do not suffer from claustrophobia,*
- *You do not have a progressive neurological condition, any serious medical or psychological diseases which are likely to seriously affect your ability to continue with experimentation.*

- *You agree to take Mini Mental State Examination (MMSE) and your MMSE score is above 21,*
- *You are not pregnant or breast feeding.*

Please note that having metallic objects on/inside you during an MEG recording would pose no risk to your health; however, these objects may typically interfere with the recording of signals.

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. You will also be asked to sign a consent form. If you choose to take part, you can change your mind at any time and withdraw from the study without giving a reason.

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

You will be invited to come for a pilot trial at the Intelligent Systems Research Centre (ISRC), Ulster University, Magee campus. You will be provided free car parking and may be paid a token amount towards your travel and subsistence expenses if you so wish. Experiments will take place in ISRC's Northern Ireland Functional Brain Mapping (NIFBM) facility where your EEG/MEG will be recorded while you are undertaking physical practice and/or mental practice of your left or right hand movements. This will involve some preparation consisting of attaching a few electrodes and head digitisation following a standard operating procedure (SOP) described in detail in the appendix. Once ready, you will wear a robotic exoskeleton on your impaired hand and be seated in an arm-chair in front of a projector or computer screen. Arrows on the screen will guide you about the hand (either left or right) to be used for performing or imagining the experimental task. A typical experimental task may consist of clenching a soft ball in one of the hands at a time. Thus, you have to either perform the task or imagine to perform it. Please note that currents or voltages will not be applied to your head at any stage. Researchers may request you to provide access to your Magnetic Resonance Imaging (MRI) report to find the location of the brain lesion due to stroke.

A typical experiment will consist of about 30 minutes of physical practice followed by another 30 minutes of mental practice of hand movements. This will be split into eight runs of 6 to 7 minutes intervals with a break of about 5 minutes between two runs. This will allow for short rest and you will be offered water and/or refreshments. Including breaks and time required for preparation, a typical experimental session will last for about two and a half hours. Only one experimental session will be conducted in a day and up to two sessions may be performed per week. A total of 20 sessions may be necessary but these will be spread over a period of several weeks. During the trial, the function of your impaired hand will be assessed by measuring the grip strength and the action research arm test (ARAT) once a week. It takes about two minutes to measure the grip strength and it indicates how much force you exert when you close your hand. It takes about ten minutes to administer the ARAT and it represents your ability to handle objects differing in size, weight and shape. During each session you will be requested to compete two visual-analog-scale (VAS) questionnaires to let us know how motivated you were to perform the exercise and how performing the exercise affected the feeling of fatigue, if any. This should not take more than a couple of minutes. After completing at least one session, you will be requested to complete two questionnaires about usability and acceptability of the robotic exoskeleton. As part of questionnaires, you will have an opportunity to write down any other comments or to answer verbally questions about your likes, dislikes, and suggestions for improvements. These questionnaires should take about five minutes each to complete.

Furthermore, at the completion of clinical trial, you may be requested to share your experience regarding the experiment and the related improvements in your day-to-day life (if any). During this session, video/audio-recording will be performed at ISRC's Northern Ireland Functional Brain Mapping (NIFBM) facility by any of the researchers involved in this study and will take 5-10 minutes. This video/audio session is completely optional. In case, you are willing to perform this, you will be requested to sign a specific consent form. The video/audio files will be used solely for the purpose of research and/or teaching, and securely stored with the chief investigator. These video/audio files will not be uploaded on any of the social

networking sites. Neither your name nor any other identifying information will be associated with the audio or audio/video recording.

7. What about side effects?

There are no known side effects of the proposed study.

8. Risks and/or disadvantages?

There are no known risks involved in the experimental work, and this is a standard procedure which has been performed for the past several years.

9. Are there any possible benefits in taking part?

At this stage, we are testing whether people with stroke can use the system correctly on repeated occasions. There may be some individual benefits as you will be thinking about moving your affected hand and actually moving your affected arm. However, this is not the focus of the current study. We hope that by completing this study we can then test the effect of this intervention on recovery of the arm and hand in a future study. So, it is to be noted that the system is not yet available for general use and if you find a benefit from using the system, you may neither get to keep it nor be able to buy/obtain it.

10. What if new information becomes available?

If new information becomes available during the course of the study, you will be kept informed and any options or requests/requirements will be fully explained. With your consent, appropriate new information about your health may be passed on to your GP.

11. What happens when the study ends?

At the end of the study, you may be contacted for further participation in the experimentation to study the performance improvement gained with the new developments. You will however not be expected to do any further experiments unless you are happy to do so.

12. What if something goes wrong?

It is very unlikely that anything will go wrong. It should be noted that the University has procedures in place for reporting, investigating, recording and handling unfavourable events. Participants should inform any complaint to the Chief Investigator or the Research Governance section of Ulster University directly.

13. Will my taking part in this study be kept confidential?

The data obtained from the study will be held securely on a university server and in confidence and any identifiers will be removed prior to publication as required under Data Protection legislation. However, the Freedom of Information legislation will allow access to certain non-personal or generalized data.

14. What will happen to the results of the study?

The results of the study will be published as research papers in academic conferences and journals. The research papers will, however, be written using anonymised data only and participants cannot be identified from the published results. The results may lead to further research or improvement in BCI and neuro-rehabilitation system.

15. Who is organising and funding the research?

The study is funded through UK India Education and Research Initiative (UKIERI) phase-3 project: Advancing MEG based Brain-Computer Interface Supported Upper Limb Post-Stroke Rehabilitation (DST-UKIERI-2016-17-0128).

16. Who has reviewed this study?

The application for this study has been reviewed by the Health & Social Care Research Ethics Committee B (HSC REC B).

17. Contact details

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Appendix

Standard operating procedure (SOP) for data recording using Magnetoencephalography (MEG):

The MEG recordings allow researchers to detect brain responses as they happen and to work out where they happen. To allow researchers to pinpoint the location of certain brain activity, participants have a model of their head created before the MEG recording; a process known as head digitisation. The following are the main steps of the standard operating procedure used in EEG/MEG scanning.

a) *First of all, a trained researcher will provide a briefing about the MEG characteristics, the tasks to be performed and what you should do and avoid during the performance of the study tasks.*
b) *You will be screened for all the possible conditions to check that you are a suitable participant for the MEG study (e.g. possible metallic implants, braces, surgical aneurysm clips, and also for medical conditions that might disqualify you as a volunteer).*
c) *If everything is fine, pre-recording preparations will be done on a special chair. For concurrent MEG-EEG recording, you need to wear an EEG cap and you will undergo the same preparation as for normal EEG recording. It may take up to 45 min for EEG preparation. This part may be skipped if the study only requires MEG recording as explained next.*
d) *As part of head digitisation, 4 or 5 head position indicator (HPI) electrodes will be attached to your head using durapore tape. These electrodes allow to track head movement during the scanning. Then locations of HPI electrodes and your whole head will be marked using a stylus pen in order to obtain a head shape that can be utilised afterwards in data analysis process. While the researcher is tracing along your scalp with the digital pen you will feel no pain and will have no evidence afterwards that this non-invasive process has been carried out. It might take approximately 15 minutes for head digitisation.*
e) *A set number of EMG electrodes will be attached to one of your arms to measure muscle activity.*
f) *Finally, you will be taken into the MSR and seated on the MEG chair and your head will be placed inside the MEG helmet as close as possible to the top of the helmet surface. You will be advised to keep still and relaxed during the recording and perform the study tasks.*