



PARTICIPANT INFORMATION SHEET

PROJECT TITLE: Can Restorative Brain-Computer interfaces Improve Hand Motor Functions after Stroke?

COMMITTEE APPROVAL NUMBER: H-2020-147

PRINCIPAL INVESTIGATOR: Professor Derek Abbott

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

The human brain is capable of change throughout life. These changes are the basis for modifications in behaviour. For example, when you learn a new motor skill, such as playing a piano, the motor regions of the brain change. These modifications allow you to improve your performance. In case of stroke patients, the lack or deficiency in movement are caused by damage to specific parts of brain in charge of sending movement commands to muscles.

A specific form of neurofeedback training may allow us to re-route the damaged neural networks caused by stroke. In this study we are going to investigate whether and to what extent neurofeedback training can fix the area of the brain, which is responsible for the control of movement.

This study may not directly benefit the participants; however, it may allow the investigators to proceed with their quest for improved treatments of stroke.

Who is undertaking the project?

This project is being conducted by Prof Derek Abbott and colleagues at the University of Adelaide and is sponsored by RehabSwift Pty Ltd.

Why am I being invited to participate?

You are being invited as you are a stroke survivor and have passed the following inclusion criteria:

(i) being at least six months post-stroke and in a stable condition; (ii) having impaired hand movement; (iii) having intact cognitive functions; (iv) being independently mobile—with or without a walking aid; (v) not having excessive spasticity in their arm and hand muscles; (vi) having the ability to undergo neurofeedback training; (vii) having a functional sense of proprioception in their affected hand—the ability to know the position of their hand joints without visual feedback ; (viii) ability to fully understand and comprehend auditory instructions presented in English.

What am I being invited to do?

You are being invited to attend a number of neurofeedback training sessions. During each session, you will be seated in a comfortable arm chair while imagining four-finger extension of your affected hand. Your brain activity during imagination of movement will be decoded via a machine learning algorithm and will be transformed to actual finger extension via a bionic hand involving with your fingers. Every session includes eight runs of neurofeedback training, where each run includes conducting 20 hand movement

imagination and relaxation trials in a randomised order. There will be 2-minute breaks between consecutive runs and collectively each session is expected to take approximately one hour.

The experiments will be conducted either in ThinLab, the University of Adelaide (Ground Floor, 10 Pulteney Street, Adelaide, SA 5000) or Queen Elizabeth Hospital (28 Woodville Rd, Woodville South SA 5011).

How much time will my involvement in the project take?

The experimental process will take approximately 20 sessions, including 18 1-hour neurofeedback training sessions and two 2-hour screening sessions during which, hand movement of the participants are monitored.

The 18 training sessions will take place within 6 weeks on 3 session per week basis. The screening sessions will be conducted before and after training sessions.

Are there any risks associated with participating in this project?

Neurofeedback training is a safe and non-invasive method. A potential burden of taking part in neurofeedback training may include fatigue and feeling exhaustion after the session. Also, having unrealistic expectation from the intervention may lead to dissatisfaction after taking part into the study.

In case you express distress, you will be referred to a suitable clinician such as your GP, neurologist or psychologist. If you do not have any specific preferences, then the research team will select a suitable clinician/psychologist for you. In any case, you will be reimbursed for the cost of visiting clinicians/psychologists due to the potential distress occurred as a result of the study.

The potential burden of feeling exhausted will disappear after few hours of rest. Also, you should be aware that you may or may not benefit from the study and any potential improvements may or may not be significant.

What are the potential benefits of the research project?

Taking part in the study may improve your affected hand's movement. However, the amount of improvement cannot be anticipated and the level of improvement may or may not be significant.

Can I withdraw from the project?

Participation in this project is completely voluntary. While completion of whole training sessions would maximise the potential recovery outcomes, you can withdraw from the study at any time and withdrawing from the project will not affect your other medical treatment/access to rehab.

What will happen to my information?

Confidentiality and privacy: In reporting the outcomes of the study, only pseudonyms will be used. Note that, while all efforts will be made to remove any information that might identify you, as the sample size is small, complete anonymity cannot be guaranteed. However, the utmost care will be taken to ensure that no personally identifying details are revealed.

Storage: Since data analysis does not require identifying individuals involved in the study, all recorded data during the study will be stored in a de-identified format and will be available to relevant bodies to

conduct the data analysis without having access to the identity of individuals. The data will be recorded in computers of RehabSwift Pty Ltd and will be kept for at least 7 years.

Publishing: The outcome of the study may be communicated using a number of channels including: journal articles, book chapters, conference papers, websites, in the media, and presentations. In all forms of communication, data will be published in a de-identified format.

Sharing: All participants will be sent a copy of the published journal/conference paper via their preferred method of delivery (email or mail). Your information will only be used as described in this participant information sheet and it will only be disclosed according to the consent provided, except as required by law.

Future use of data: The de-identified recorded data and test results may be used for next phases of the research as well as for sharing the data with other researchers in the field.

Who do I contact if I have questions about the project?

If you have concerns either before or following the experiment, please contact one of the researchers listed at the end of the document

Sponsorship

Dr Sam Darvishi is the founder and director of RehabSwift Pty Ltd, which sponsors this study. This study is based on Dr Darvishi's prior research and his contribution in the design of the study, training and assisting with running neurofeedback sessions is essential. However, Dr Darvishi will not have any roles in the assessments of patients and the analysis of the data.

What if I have a complaint or any concerns?

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (approval number H-2020-147). This research project will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator. If you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant, please contact the Human Research Ethics Committee's Secretariat on:

Phone: +61 8 8313 6028

Email: hrec@adelaide.edu.au

Post: Level 4, Rundle Mall Plaza, 50 Rundle Mall, ADELAIDE SA 5000

You can also contact Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) using the following contact details:

Reviewing HREC name	Central Adelaide Local Health Network HREC
Contact	Executive Officer
Telephone	08 7117 2229 or 08 8222 6841
Email	Health.CALHNResearchEthics@sa.gov.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

If I want to participate, what do I do?

In order to join the study, contact Associate Professor Anupam Datta Gupta via email or phone to book a screening appointment.

Yours sincerely,

Professor Derek Abbott

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