

Plain Language Statement: Effects of BCI training for people with upper limb dysfunction due to stroke



Department of Biomedical Engineering, The University of Melbourne

Responsible Researcher:	A/Prof. Sam John sam.john@unimelb.edu.au	+61 383 449 437
Experimenting Researcher:	Mr. Kadir Ergene kergene@student.unimelb.edu.au	
Additional Researchers:	Prof. David Grayden grayden@unimelb.edu.au Dr. Maya Panisset maya.panisset@unimelb.edu.au	

Introduction

We would like to invite you to participate in a project on upper limb rehabilitation using brain-computer interface. Brain-computer interfaces (BCIs) are a technology that can measure, interpret, and make use of brain activity with sensors placed on a person's scalp to control computers or devices. BCI training has been shown to improve recovery of people with stroke over a long intervention period; however, there is a gap in our understanding on how BCI training promotes changes in brain activity and physical performance over a single session. BCIs can provide feedback on both physical and mental exercise, however the relationship between physical and mental exercise, and their comparative effects on stroke recovery remain unresolved. Likewise, the effect of session duration in BCI-based therapy is unexplored.

The aim of this project is to investigate the effect of a BCI intervention involving physical and mental exercise on the neural activity of stroke patients with upper limb symptoms. Neural activity will be measured during the BCI intervention, as well as before and after the intervention. This experiment involves taking part in 4 upper limb rehabilitation sessions, each approximately 1.5 hours in duration.

What will I be asked to do?

If you choose to participate, you will be asked to attend the University of Melbourne, Biomedical Engineering building (building 261) on 203 Bouverie St, Carlton VIC 3053, once per week, for three consecutive weeks. You can park in the University Square car park accessible through 244 Bouverie Street. There is also 2-hour street parking all along Bouverie Street.

In each session, you will be asked to perform a set of physical and/or mental exercises for 10 minutes at a time, 4 times, with breaks of 5 minutes in between. At the beginning of each session, you will also be asked to perform a set of functional assessments which will test your

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hand and arm function. We may ask to take a video recording of you completing these assessments to check back on and confirm results. Throughout the sessions, you will also complete 3 different questionnaires through on a computer.

Electroencephalography (EEG) is the electrical activity of brain activity, while Electromyography (EMG) is the electrical activity of muscle activity. Throughout the duration of each session, you will wear an EEG headcap with sensors on the inside (shaped like little combs) connected to a computer which will measure brain activity (called EEG) and provide you feedback during the exercises. We will also place small adhesive sensors on the skin of your forearm to record muscle activity (called EMG). At the start of each session, we will place these devices on you which we will remove at end of each session.

In the case of EEG, sensors will be embedded in a fitted cap worn by participants. The cap contains flexible comb-like electrodes designed to pass through the hair and contact the scalp. Each electrode is individually adjusted to ensure proper contact and signal quality. For EMG, disposable adhesive electrodes will be placed on the skin over the forearm and elbow, after the areas have been cleaned with alcohol wipes.

What are the risks?

During participation in this study, researchers will monitor for and minimise environmental risks which may contribute to trips and falls. Experimenting researchers will monitor for hazards and guiding participants through the facility. Along with environmental risks, researchers will monitor for cardiovascular incidents, seizures, and fainting, and contact 000 when required.

EEG sensors may require the use of gel to improve skin conductivity and signal quality, which along with wearing the cap itself, might contribute to skin irritation in some. EMG sensors are pre-gelled and may cause similar irritation. Participants may stop the experiment at any time and are encouraged to do so if they notice skin irritation and will be offered to be taken to a washroom to clean any areas where gel was applied.

This experiment will involve the completion of mental and physical exercise which may induce mental and physical fatigue in some, contributing to muscular weakness, tiredness, and low mood for a short time. To minimise this, participants will be given regular breaks throughout the duration of the experiment and will be given time at the end of the session to rest and recover before leaving the facility.

Throughout the duration of the experiment, participants will be encouraged to communicate any discomfort they experience. If you feel emotionally affected or distressed

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during or after participating, support services such as LifeLine (13 11 14) or the University of Melbourne Psychology Clinic (Tel: +61 3 9035 5180, email: clinic@psych.unimelb.edu.au) are available for assistance.

What are the benefits?

This study has the potential to contribute to better rehabilitation strategies for stroke patients by improving the effectiveness of BCI-based interventions. The results may guide the development of more adaptive and personalized rehabilitation protocols for stroke recovery. As a token of our appreciation, participants will receive a \$50 gift card upon completing the study. The findings from this study may be published in academic journals or presented at conferences to allow other researchers to further improve upon these findings.

How will my confidentiality be protected?

Your confidentiality will be protected throughout the study. All data collected during the study will be de-identified and digitised (if not already digital) and securely stored indefinitely on password-protected servers. Only authorized researchers will have access to the data. Video recordings, if taken, will be used to verify results and for scientific journal publications and conference presentations and will not include identifiable information. De-identified data may be used in future research, but personal information will not be kept, shared, or published.

What if I want to withdraw from the research?

Participation in this research is completely voluntary. You are free to withdraw at any time and to withdraw any unprocessed data previously supplied. Withdrawing from the research would have no effect on your relationship with any member of the University of Melbourne.

Where can I get further information?

If you have not understood any of this information, please contact any of the researchers listed above. This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project that you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010.

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Department of Biomedical Engineering, The University of Melbourne

Tel: +61 3 8344 1376 or

Email: research-integrity@unimelb.edu.au

All complaints will be treated confidentially. In any correspondence, please provide the name of the research team, or the name or ethics ID number of the research project.

How do I agree to participate?

If you wish to participate, please read and sign the consent form provided by the researcher.

Department of Biomedical Engineering

The University of Melbourne, Victoria 3010 Australia

T: +61 3 8344 9437

W: <http://www.bme.unimelb.edu.au>