Document: Informed consent form

Official study title: Error augmentation for upper limb rehabilitation in stroke survivors

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Error augmentation for upper limb rehabilitation in stroke survivors

INFORMED CONSENT FORM
INDIVIDUALS WHO HAVE HAD A STROKE

1. STUDY TITLE

Error augmentation for upper limb rehabilitation in stroke survivors

2. PRINCIPAL INVESTIGATORS

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3. COLLABORATORS

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4. INTRODUCTION

We are inviting you to participate in a research project. Before agreeing to participate in this project, please take the time to read and carefully consider the following information.

This consent form explains the aim of this study, the procedures, advantages, risks, and inconveniences, as well as the persons to contact, if necessary.

This consent form may contain words that you do not understand. We invite you to ask any question that you consider useful to the investigator and the other staff members assigned to the research project and ask them to explain any word or information that is not clear to you.

5. DESCRIPTION OF THE PROJECT AND ITS OBJECTIVES

A new technology has been developed that uses robotics and virtual reality to create a training environment for the upper limb of people who have had a stroke. In this project, two studies will be done. The objective of the first study is to compare motor learning in healthy people using two different learning strategies. The objective of the second study is to test the technology in people who have had a stroke. You will participate only in the second study.

6. NATURE OF PARTICIPATION

If you accept to participate, your participation in this project will consist of 3 training sessions with the new technology and clinical evaluation sessions before and after the trainng sessions. The 3 sessions will be separated by at least 1 day. The sessions will be held at the Sensorimotor Control and Rehabilitation Laboratory at the Jewish Rehabilitation Hospital.

Session 1 (1 hour and 15 min): We will evaluate the movements of your more-affected arm (Fugl-Meyer Assessment), and spasticity in your elbow flexors (Modified Ashworth Scale, TSRT test). The TSRT test consists of stretching your elbow 20 times while muscle signals and movements of your arm are recorded with surface electrodes and a goniometer respectively. The evaluation session will take approximately 45 minutes. Then, you will do a short pre-test evaluation where we will record the movement of your upper limb in 10 trials and you will be asked to practice reaching using a robot and virtual reality system for 30 minutes. At the end of the training session, we will ask you to rate how hard you were working during the reaching practice.

Session 2 (1 hour): This session consists of measuring the TSRT as described above and then 30 minutes of reaching training in virtual reality with the robot, following which, we will ask you to rate how hard you were working during the session.

Session 3 (2.5 hours): This session also consists of measuring the TSRT and 30 minutes of reaching training as in Session 2 and rating of how hard you worked. Following the session, we will repeat the clinical evaluations mentioned in Session 1 (Fugl-Meyer Assessment, Modified Ashworth Scale, TSRT test) and perform a short post-test of 10 reaching movements. Then, after a rest period of 1 hour, we will repeat the Modified Ashworth Scale, TSRT and 10 reaching movement (follow-up) tests again.

7. PERSONAL BENEFITS OF PARTICIPATING IN THE STUDY

As a participant in a research study, you will not benefit directly from the study. However, information gathered in this study may contribute to the development of better tools to re-train movement of the upper limb.

8. RISKS AND INCONVENIENCES ASSOCIATED WITH PARTICIPATING IN THE STUDY

It is understood that your participation in the study will not affect the care and services you receive or will receive from your rehabilitation institution.

There are no risks involved with the measurement of spasticity with the MSRT or with the clinical measures that are commonly used.

Recording of muscle responses: The strictest rules of hygiene (hypoallergenic adhesive tape and cleaning skin with alcohol) will be applied. Despite the application of these hygiene measures, there is a possibility of skin irritation where electrodes are attached. In these cases, a soothing lotion will be applied to your skin.

INCONVENIENCE

- Travel / participation time: The travel time from your home to the research site as well as the participation time in the research project may represent an inconvenience for some people.
- Fatigue may occur during the trial. In order to minimize fatigue, rest periods of 5 minutes or more will be offered when requested.

9. ACCESS TO THE RESULTS AT THE END OF THE RESEARCH

At the end of the study, you will have the possibility of access to the general results of this research project.

Yes ☐

No ☐

Email: _____

Mailing address: _____

10. ACCESS TO YOUR MEDICAL RECORD

You authorize the research team to consult your rehabilitation record in order to collect information in relation to stroke (lesion type/location, medical history, upper limb motor ability, perception and/or cognitive ability) necessary to conduct the research project. Only information related to the project objectives will be accessed.

11. CONFIDENTIALITY

All personal information collected concerning you during the study will be coded to ensure its confidentiality. Only the members of the research team will have access to it. However, for research project control purposes, your research record could be consulted by a person mandated by the REB of the CRIR institutions or by the Direction de l'éthique et de la qualité du ministère de la Santé et des Services sociaux du Québec This person adheres to a policy of strict confidentiality.

The research data (paper and video recordings) will be kept under lock and key at the Jewish Rehabilitation Hospital by the person in charge of the study for a period of 7 years following the end of the project, after which it will be destroyed. In the event that the results of this study are presented or published, no information that can identify you will be included.

12. VOLUNTARY PARTICIPATION AND RIGHT OF WITHDRAWAL

It is understood that your participation in this research project is completely voluntary and that you remain free to terminate your participation at any time without having to give a reason and without suffering any prejudice of any kind.

13. SUBSEQUENT STUDIES

It is possible that the results of this study will give rise to another research project. In this context, do you authorize the persons in charge of this project to contact you again and ask if you would like to participate in this new project?

- ☐ no
- ☐ yes, for one year *
- ☐ yes, for two years *
- ☐ yes, for three years *

* Note, if you check off one of these three options, your personal contact information will be kept by the Principal Investigator for the period which you have selected.

14. RESPONSIBILITY OF THE RESEARCH TEAM

By accepting to participate in this study, you do not renounce any of your rights nor do you release the investigators or the institution involved from their civil or professional responsibilities.

15. COMPENSATORY INDEMNITY

For your participation in this research project and the related constraints (e.g. travel costs), an indemnity of $30 CAD per session will be provided by the person in charge of the research project.

16. RESOURCE PERSONS

If you have any questions regarding the research project, if you wish to withdraw from this study or if you wish to inform the research team regarding an incident, you may contact: Mindy F. Levin, PhD, PT, Professor, McGill University, at (450) 688–9550, extension 3834, or by email (mindy.levin@mcgill.ca).

If you have any questions regarding your rights and responsibilities or your participation in this research project, you may contact Mme Coralie Mercerat, Research Ethics Coordinator for the CRIR's institutions, at (514) 527-9565, extension 3789 or by email at the following email address: coralie.mercerat.ccsmtl@ssss.gouv.qc.ca.

For these questions, you may also contact the local patient ombudsman at your establishment (see list below).

17. CONSENT

I declare that I have read and understood this project, the nature and the scope of my participation, as well as the risks and inconveniences to which I may be exposed, as presented in this document. I have had the opportunity to ask all my questions regarding the different aspects of the study and to receive answers to these questions. A signed copy of this information and consent form must be provided to me.

I, undersigned, voluntarily accept to participate in this study. I can withdraw my participation in this study at any time without prejudice of any kind. I certify that I was allowed all the time necessary to make my decision.

Participant's Name: SIGNATURE

_____ _____

Signed at _____ on _____, 20_____

THE RESEARCHER MUST GIVE A SIGNED COPY OF THE CONSENT FORM TO THE PARTICIPANT AND KEEP ANOTHER ONE IN THE RECORD

18. COMMITMENT OF THE INVESTIGATOR OR HER/HIS REPRESENTATIVE

I, undersigned, _____, certify:

(a) that I have explained to the signatory the terms of the present form;
(b) that I have answered any questions that she/he asked me in this regard;
(c) that I have clearly indicated that she/he remains, at any time, free to terminate her/his participation in the research project described above;
(d) that I will provide her/him a signed and dated copy of this form.

_____
Signature of the Principal Investigator or his representative

Signed on _____ of _____, 20_____

Contact information for Local Complaints Commissioners:

Jewish Rehabilitation Hospital (JRH, CISSS Laval): (450) 668-1010, extension 23628 or plaintes.csssl@csss.gouv.qc.ca

Institut universitaire en réadaptation en déficience physique de Montréal: (514) 593-6300

Richardson Hospital: (514) 340-8222, extension 25833