A piano training program to improve manual dexterity and upper extremity function in subacute stroke survivors

October 1st, 2024

INFORMED CONSENT FORM

1. STUDY TITLE

A piano training program to improve manual dexterity and upper extremity function in subacute stroke survivors

2. PRINCIPAL INVESTIGATORS

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3. FUNDING AGENCY

This research project is funded by the Vitalise project (European Commission) and by a salary support grant from the Jewish Rehabilitation Hospital Foundation.

4. INTRODUCTION

We invite you to participate in a research project examining the use of piano training in rehabilitation. 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

People who have suffered a stroke often experience weakness in the affected hand and difficulty in manipulating objects. This can have a negative impact on activities of daily living (such as grooming, preparing meals, writing by hand or on the computer). Studies have shown that musical training, that is playing an instrument such as the piano, can improve the recovery of arm and hand movements following a stroke, even in people with no musical experience. These improvements are thought to be due not only to intensive practice of finger movements, but also to changes in the brain areas responsible for hearing and controlling finger movements. However, we do not know whether it is feasible to offer such a training program in a way that is integrated with usual rehabilitation care.

Primary objective of this study: The primary objective of this project is to study the feasibility of a 6-week piano training intervention for stroke patients in the 'congé précoce assisté' program (early supported discharge program) or the outpatient rehabilitation program at the Jewish Rehabilitation Hospital.

Secondary objective: The secondary objective of the project is to compare the effects of piano intervention versus conventional therapy on dexterity, coordination and daily use of the affected hand. The aim of this objective is to use these data to support a future larger study.

6. NATURE OF PARTICIPATION

This study involves two groups of participants, each receiving additional therapy time compared to usual care. You will be "assigned" to one of the two groups at random, as if you were "flipping a coin". Therefore, you'll have an equal chance of being placed in either of the 2 groups.

In addition to the usual care, **group 1** will receive piano training sessions, while **group 2** will receive occupational therapy sessions. Details of the sessions are given below. **Please note that prior piano experience is not required to participate in this research.**

For both groups, your participation includes:

- **Twelve (12) 45-minute therapy sessions** over a 6-week period (2 sessions per week). During these 6 weeks, you will be required to perform **two (2) weekly home practices** of 15 minutes each.

- **Three (3) evaluation sessions** over a 12-week period, the first before the start of training, the second after the end of training and the third six (6) weeks after the end of training.

Participants in the '*Congé Précoce Assisté*' Program who receive their usual therapies at home will also receive their additional therapies at home, including assessments and training sessions. One of our team members (instructor) will come to your home according to a pre-established schedule and your availability. Should you be transferred to the outpatient rehabilitation program, your training and assessment sessions will continue at the Jewish Rehabilitation Hospital, again according to an established schedule and your availability.

Participants in the Outpatient Program receiving their usual therapies at the Jewish Rehabilitation Hospital will also receive their additional therapies at the hospital, including assessments and training sessions. One of our team members (instructor) will accompany you during each of your sessions, according to a pre-established schedule based on your availability.

The Jewish Rehabilitation Hospital is located at 3205, Place Alton-Goldbloom, Laval (Qc), H7V 1R2.

Below is a description of the therapy sessions:

Group 1:
1. Piano training sessions (duration: 45 minutes/session): Training consists of learning and practicing various simple musical pieces with your affected hand. Training will be done using an electronic piano connected to a computer. This equipment will be brought to each session by the instructor for participants receiving home sessions. This person will also guide you during the training.

2. Home practice sessions (duration: 15 minutes/session): The home practice program consists of practicing the pieces learned with the instructor, using a small flexible piano that will be loaned to you by the research team. You will also be asked to write down the duration and content of each of your practice sessions in a logbook.

3. Assessment sessions (duration: 1h30/session): Five (5) tests will evaluate your dexterity and coordination in your hands and arms. To do this, we will ask you to manipulate various objects (e.g. blocks, wooden pegs, spoons, cards, cans, etc.). Three (3) tests will also assess your level of depression and anxiety, as well as your general experience by asking you various questions.

Group 2:
1. Occupational therapy session (duration: 45 minutes/session): Training consists of various occupational therapy activities and exercises and will be provided by a licensed occupational therapist. These exercises will be selected from your treatment plan, which will be provided by your rehabilitation team. Examples include mobility exercises, activities of daily living, information sessions, etc.

2. Home practice session (duration: 15 minutes/session): Home practice consists of exercises that will be provided by the occupational therapist. You will also be asked to record the duration and content of each training session in a logbook.

3. Assessment sessions (duration: 1h30/session): Five (5) tests will evaluate your dexterity and coordination in your hands and arms. To do this, we will ask you to manipulate various objects (e.g. blocks, wooden pegs, spoons, cards, cans, etc.). Three (3) tests will also assess your level of depression and anxiety, as well as your general experience by asking you various questions.

You can take as many breaks as you need during training and evaluation sessions.

7. PERSONAL BENEFITS OF PARTICIPATING IN THE STUDY

This study offers you the possibility of increasing the number of therapy sessions. This increase in intensity is likely to have a beneficial impact on your condition. In any case, you could be contributing to the advancement of science in the field of stroke rehabilitation.

8. RISKS AND INCONVENIENCES ASSOCIATED WITH PARTICIPATING IN THE STUDY

Risks: There are no known risks associated with participation in this study.

Inconveniences:
1. Duration of participation: The time associated with participation can be an inconvenience.
2. Piano training: You may feel tired after training, but this will be temporary. If you become tired during the session, you will be able to rest before continuing.

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

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

Yes ☐

No ☐

Email or address: _____

10. PRECAUTIONS COVID-19

Strict precautions are taken by our team to ensure the safety of all participants and research team members. Before coming to your home, you will be asked if you have any symptoms related to COVID or the flu, in which case the testing session will be postponed until you are symptom-free. Similarly, members of the research team who have symptoms related to COVID or the flu will not come to your home. The research team will thoroughly clean all equipment before and after arrival each session, using disinfectant wipes approved by the Jewish Rehabilitation Hospital. We will follow the procedures issued by CISSS-Laval regarding the wearing of surgical masks by members of the research team and/or participants.

11. CONFIDENTIALITY

All personal information collected about you during the study will be coded to ensure confidentiality. Only members of the research team will have access to it. However, for research project control purposes, your research file may be consulted by a person mandated by the *Comité d'éthique de la recherche en réadaptation et en déficience physique* or by the *Direction de l'éthique et de la qualité of the Ministère de la Santé et des Services sociaux du Québec*, who adheres to a strict confidentiality policy. Electronic research data will be stored on password-protected external hard drives, and hard copies of research data will be stored in a locked cabinet in the office/laboratory of the principal investigator (Anouk Lamontagne, PhD at the Jewish Rehabilitation Hospital). Electronic data and paper copies will be kept for a period of 7 years following the end of the project, after which they will be destroyed.

12. SECONDARY USE OF INFORMATION FOR RESEARCH PURPOSES

Online storage of electronic research data

In addition, by participating in this study, your anonymized (non-identifying) electronic research data could be stored in McGill University's Dataverse research data registry, which is part of the Canadian Dataverse registry. This open-access online data registry is hosted in Canada and enables research data to be stored securely. The research team's management of this data will respect current standards, as well as the provisions of the Personal Information Protection and Electronic Documents Act (PIPEDA). This initiative to store data in a registry was adopted in response to a recent request from funding agencies and publishers, who sometimes encourage or require researchers to make their data accessible at the end of their study. Making research data available enables qualified researchers to reproduce scientific results and stimulates exploration of existing datasets. Do you agree to your data being used for this purpose?

☐ Yes ☐ No

The information you provide may be used, before the expected date of its destruction, in other research projects that will focus on the different facets of the topic for which you are solicited today. These possible projects will be the responsibility of the principal investigator and will be authorized by the *Comité d'éthique de la recherche en réadaptation et en déficience physique*. The research team is committed to maintaining and protecting the confidentiality of your data under the same conditions as for this project. Do you agree that your data can be used in this context:

☐ Yes ☐ No

13. VIDEO RECORDING AND/OR TAKING PHOTOGRAPHS

It is possible that certain sessions will be recorded via videos or that photographs will be taken of you. We would like to use these recordings or photographs, with your permission, for the purpose of training and/or scientific presentation purposes. These videos/photos will be taken in such a way that you cannot be identified (e.g. face blurred or with face out of frame). However, it is unnecessary to consent to this in order to participate in this project. If you refuse, the recordings and photographs concerning you will be destroyed at the end of the project to respect your confidentiality. If you accept, your face will be blurred.
Do you authorize us to use your photographs or recordings for the purpose of training or scientific presentations and to keep these recordings with your research data?

Yes ☐ No ☐

14. VOLUNTARY PARTICIPATION AND RIGHT OF WITHDRAWAL

You are free to accept or refuse to participate in this research project. You may withdraw from this study at any time, without having to give a reason and without suffering prejudice of any kind. You simply have to notify the resource person of the research team. In case of withdrawal on your part, the visual and written documents concerning you will be destroyed at your request.

15. 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 Lead Investigator for the period which you have selected.

16. 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 institutions involved from their civil or professional responsibilities.

17. COMPENSATORY INDEMNITY

You will receive $30 for each session (evaluation and training) held at the Jewish Rehabilitation Hospital, to cover your travel expenses. Participants receiving their sessions at home will receive $30 for each evaluation session and $10 for each training session, in consideration of the constraints and inconveniences resulting from their participation in the research project.

18. RESOURCE PERSONS

If you have any questions about the research project, wish to withdraw from the study or wish to report an incident to the research team, you can contact Anouk Lamontagne at 450-588-9550 ext. 84168, or by e-mail at anouk.lamontagne@mcgill.ca.

If you have any questions about your rights and recourse, or about your participation in this research project, you can contact the *Comité d'éthique de la recherche en réadaptation et en déficience physique* (CER RDP) at 514-809-0230, or by e-mail at cer.rdp.ccsmtl@.gouv.qc.ca

To file a complaint, you can contact the local complaints commissioner at Jewish Rehabilitation Hospital at 450-688-1010 ext. 23628, or by e-mail at plaintes.csssl@ssss.gouv.qc.ca.

19. 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 on _____ of _____, 20_____

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

20. 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 Lead Investigator or his representative

Signed on _____ of _____, 20_____