Consent Form to Participate in a Research Study for Stroke Survivors

Study title: Development of a Gamified Modular Robotic Rehabilitation System to Enhance Motivation and Engagement in Post-Stroke Upper Limb Independent Exercises

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Introduction

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study team to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish.

Background and Purpose

Stroke is the number one cause of serious, long-term disability worldwide. It happens to about 15 million people every year and can lead to a wide range of issues that affect the mind, sight, and movement. The arms are often affected because they're controlled by a large portion of the brain, and when a stroke happens, they may lose movement, coordination, feeling, and the ability to handle objects well. This can make everyday tasks hard and may lower the quality of life for those who've had a stroke. Early in recovery, doing these movements many times (between 300 to 600) is crucial for getting better. However, in usual therapy sessions, patients might only do up to 70 of these movements. To make up for this, patients are given exercises to do at home. But, not many people follow through with these home exercises due to feeling bored, not confident enough, or finding it hard to do them without someone to guide them.

To improve recovery over the long term, we need to find ways to make rehab better and more engaging, not just in therapy centers but also at home. One exciting idea is to make exercises more like games, which can make them more fun and motivating. This approach can help people stay interested in their exercises, feel more confident, and enjoy their progress. Using robots and computer games for hand and arm rehab is a promising way to offer personalized, intensive practice that people can do remotely. Although there are many advanced robots designed for rehab, they are often too expensive and complex for widespread use. Most are not suitable for home use because they are either too simple, only focus on a few movements, or require a professional to be present.

Recently, there's been more emphasis on care that focuses on the patient's needs and preferences, especially in rehab, which is a long and changing process. For robotic devices to be helpful in therapy, they need to be adaptable and durable. There's a need for systems that can be tailored to each person's specific needs and can change as the person's recovery progresses.

The focus of this study is to apply a user-centred approach to design and build a cost effective, modular, and easy-to-use rehabilitation platform for post-stroke rehabilitation. Our objective is to develop a platform that not only maintains patient engagement but also offers essential feedback for the accurate execution of exercises with little to no supervision, while efficiently monitoring their progress over time. The platform's usability, specifically focusing on user satisfaction and effectiveness in performing independent exercises will be measured through user satisfaction and expert observational assessments, with iterative enhancements informed by user and expert feedback collected via structured questionnaires.

Description of the Study

You are invited to engage in a study that aims to refine a rehabilitative platform for stroke survivors. This study is expected to involve 5 to 10 stroke survivors as well as up to 5 clinical experts (physiotherapist and occupational therapists) and will last for several months, with intermittent sessions. You are asked to interact with a developed system and complete a questionnaire at the end of the session. To join this study, you should be able to sit steadily for at least a minute and a half to do arm exercises with our robotic system. Your stroke should have happened within the last year, and it should have affected one arm. It is expected that each session will run for approximately 60 to 90 minutes with the maximum 10 number of sessions in total. The sessions will take place in a meeting room at 500 University Avenue, Toronto. The sessions will be video and audio recorded. This data will be used as a reference by the team when improving on the next iteration of the prototype's design. It will be possible to identify you on the video and audio recordings. If used for presentations, you would not be identifiable. Both your video and voice data will be kept confidential as per the policy defined in Confidentiality section in this form. Each session will include the following steps:

1. Introduction to the research team, a comprehensive explanation of the study's objectives, and collection of informed consent documents (first session only).
2. Initial assessment of participants' arm function and cognitive abilities using standardized tests to establish baseline measures. Specifically, the Chedoke McMaster Stroke Arm Assessment, Wolf Motor Function Test (WMFT), and Montreal Cognitive Assessment (MoCA) will be conducted to ensure diverse representation of upper limb impairment in the advisory group as well as ensuring the absence of neurological or orthopedic conditions that might impact arm movement (first session only).
3. Orientation on the use of the rehabilitative platform, including the robotic device and gaming exercises.
4. Independent time given to the participants to experiment with the platform and run through some of the developed exercises and games on the platform. Each session will be monitored, with a researcher available for support and to document observations, feedback, comments.
5. A concluding assessment to evaluate overall progress and user satisfaction with the platform.

Potential Harm/Risks

We have implemented comprehensive safety measures across mechanical, electrical, and software design levels. The robotic system is constructed without sharp edges and includes physical stops to prevent any joint from exceeding the anatomical range of motion of the human limb. Emergency shutoff switches are strategically placed, with switches to terminate motor command signals and for complete power shutoff accessible to both you and the research team who will be observing and present during all sessions. Software commands limit the maximum allowable output current and torque to the motor, ensuring these are well below levels that could cause harm to human joints, with added surveillance routines for current and speed monitoring. You will be supervised by an engineering researcher at all times during the use of the system, and emergency stop switches will ensure the system can be promptly shut down if necessary. Despite these precautions, there is a potential risk of physical injury to the upper limb in case of

malfunction, with provisions in place for immediate access to first aid and emergency medical services if required. By signing this form, you acknowledge being informed of the potential risks and safety measures in place and consent in participating in the study under these conditions.

You may also encounter challenges or frustration due to the prototype nature of the system. Adequate support and guidance will be provided throughout the study. You may also feel fatigued during exercise sessions; breaks and rest periods will be incorporated as needed to ensure comfort and safety.

Potential Benefits

There are no direct benefits from participating in this study. However, you will have the opportunity to contribute to the development of innovative rehabilitation technology that could benefit future stroke survivors.

Cost and Reimbursement

We aim to achieve a technology usability score of 90+ by conducting iterative user-centered design meetings. These sessions will continue until the desired score is achieved, with a maximum of 10 sessions.

To address concerns regarding potential travel and other expenses, we confirm that a $30 reimbursement amount will be provided per session. This reimbursement is intended to cover any travel and related expenses incurred to attend the sessions at 500 University Avenue, Toronto.

Voluntary Participation

Your participation is entirely voluntary. You may decide not to be in this study, or to be in this study now and then change your mind later. You may leave the study at any time. You may refuse to answer any question that you do not want to answer.

Withdrawal from Study

You may leave the study at any time. Should you choose to withdraw from the study you are encouraged to contact Deniz Jafari at 647-456-3612 or deniz.jafari@utoronto.ca immediately.

There will be no consequences if you withdraw from this study. You will not receive the compensation if you choose to withdraw during each session. If you withdraw from the study, we will ask you whether we can keep and analyse your data or if you wish to have your data destroyed. If you decide to have your data destroyed after the study session, you can do so within 48 hours upon completion of each session. Within this time frame you can wish to have your data destroyed.

Confidentiality

If you agree to participate in the study, the researcher of the study will look at your personal information. Only the information that is needed for the study will be collected. Personal health information is any information that could identify you and includes your:

- Name
- Date of Birth (Year only)
- Image
- Audio recordings
- Video recordings
- Phone number
- Email address
- Time since stroke
- Level of impairment due to stroke

The principal investigator will keep any personal health information about you in a secure and confidential location for seven years.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Access to the data will be restricted to the supervisor and researchers of this project. The only exception to this rule would occur in the event of a research audit. In this case, research records identifying participants may be inspected in the presence of the investigator (or designate) by representative(s) of the Human Research Ethics Program (HREP). All information accessed by the HREP will be held to the same level of confidentiality that has been stated by the research team. This review would be for the purpose of monitoring the research and the inspection would not result in participant information leaving the research office. You will not be named in any reports, publications, or presentations that may come from this study.

You will be assigned a code number which will be used during the study. All data in the study will be labelled with this code. Video and audio recordings will be transferred to a UofT server/SharePoint immediately after the completion of the experiment. The data on the video and audio recorders will then be deleted. All hard copy data (i.e., paper copies) will be kept in a secure place in the supervisor Dr. Alex Mihailidis' laboratory. Electronic data (i.e., recordings) will be securely stored on the UofT servers/SharePoint. All data files will be kept strictly confidential within the research team involved in this project and will not be shared with others without your express permission. Audio and video recordings will be used solely for internal validation purposes and will not be posted or shared externally. During the sessions, you will be addressed by your names for natural interaction; however, for data analysis and publications, all identifiable information will be removed, and participants will be referred to by their specific random codes. If photos are taken, they will be blurred to ensure your anonymity if used for any publication purposes. All data will be destroyed after seven years from the date of study closure. If and only if you consent, your video data/images may be presented for educational and research purposes.

Conflict of Interest

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Rights as a Participant

By signing this form, you do not give up any of your legal rights against the investigators, or involved institutions for compensation, nor does this form relieve the investigators, or involved institutions of their legal and professional responsibilities.

You are encouraged to ask any questions about the study at any time. Your participation is completely voluntary, and you are free to withdraw from the study at any time with no consequences. Your participation or decision to not participate will have no effect on your relationship with the study team, the Intelligent Assistive Technology and Systems Lab (IATSL), or the University of Toronto. Your participation or decision to not participate will also have no effect on your employment status with any of the mentioned institutions.

Questions about the Study

If you have questions or concerns regarding the study, please contact Deniz Jafari at deniz.jafari@utoronto.ca or 647-456-3612, or Dr. Alex Mihailidis at alex.mihailidis@utoronto.ca or 416-946-8565.

If you have any questions about your rights as a research participant or have concerns about this study, please contact the University of Toronto Office of Research Ethics at ethics.review@utoronto.ca or (416) 946-3273. The Office of Research Ethics is a group of people who oversee ethical conduct of research studies. They are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

_____	_____	_____
Print name of participant	Date	Signature

_____	_____	_____
Print name of the person obtaining the consent	Date	Signature

Would you give us permission to use your video/images for scientific presentation/publication?

☐ Yes

☐ No

Would you like to be contacted for future research studies?

☐ Yes

☐ No