PARTICIPANT INFORMATION SHEET
Participant with Stroke

TITLE OF THE STUDY

Robotic-Assisted Game-Based Rehabilitation for upper limb function in people with chronic stroke: A Feasibility Study

WHO IS DOING THE RESEARCH?

Esminio L. Rivera II is a Master by Research in Physiotherapy student at UTS. This study will be supervised by the Physiotherapy academic staff of the University of Technology Sydney, Graduate School of Health: Dr. Arianne Verhagen, Dr. Camila Quel De Oliveira, Dr. Peter Stubbs and Dr. Alana McCambridge

WHAT IS THIS RESEACH ABOUT?

Nowadays, technology plays a very important role in healthcare. Novel interventions like robotics are being used to treat diseases and assist people with disabilities One of the trending applications of robotics is its use to help people after a stroke to perform exercises and improve the movements of their arms. Robotics is gaining an important role in rehabilitation, because unlike any other treatment/training to improve arm function, game-based robotic rehabilitation can 1) assists both the therapist and patients to achieve their goal better and faster; 2) it increases motivation as patients can play games while using the robots; 3) it can monitor progress and improvements of the arm; 4) it can provide a large number of repetitions, which is a very important for movement recovery after a stroke.

However, this is an area that needs more research. There are few studies that explored the opinions and views of people who had a stroke, their therapists and their carer/family about the use of robots in rehabilitation. Hence, this study aims to understand better if robot-assisted game-based rehabilitation is an accepted treatment for people after stroke. By doing this, we will understand the strengths and weaknesses of robotic rehabilitation. This study will also provide a sneak peek of the possible effects of such intervention in the arm affected by the stroke.

WHY HAVE I BEEN ASKED?

You have been invited to participate in this study because you are a person who had a stroke for at least 6 months that affected your ability to move your arm.

IF I SAY YES, WHAT WILL IT INVOLVE

If you decide to participate, you will be involved in the pre-assessment, training, post-intervention and follow up assessments; and focus group discussion phases of the study. All phases will take place at Level 2, UTS Moorepark Campus, Graduate School of Health, Physiotherapy Department Moore Park Rd and Driver Avenue Moore Park, NSW 2021.

Pre-assessment Phase

At the start, you will be asked to provide your details to the researcher, such as name/age/contact detail/details about your stroke/other health problems/cigarettes and alcohol consumption/occupation/ treatments that you are undergoing. You will also be asked to answer questions about your memory, attention span, and concentration, ability to plan and understand instructions. You will also have to provide information regarding your previous and current rehabilitation or exercise therapy that you received/receiving to the researchers.

A Physiotherapist will assess your arm movements by asking you to perform activities to evaluate muscle strength, joint motion, and coordination of your shoulder, elbow, forearm, wrist, and hand. You will also answer a questionnaire about how much and how well you can use your arm and hand during your day-to-day activities. All assessments in this phase will take approximately 2 hours.

Training/Intervention Phase

You will be undertaking an exercise program for your whole arm using robotic devices. You will undertake 10 sessions during a period of 3 weeks. Each session is 1h long and will be supervised by a therapist trained to use the robots. When using the device, you will be seated in front of screen playing games. There are three robotic devices and they are demonstrated below:

SHOULDER TRAINING

ELBOW-FOREARM TRAINING

HAND TRAINING

Image source: Tyromotion User Manual

Post-intervention and Follow-up assessments

Immediately after your last session and one week after the last session, the function of your arm will be reassessed by a Physiotherapist using the same process mentioned in the pre-assessment phase. Also, you will be asked to answer a questionnaire about the usefulness and your opinion about the devices during the post-intervention assessment. Both post-intervention and follow-up assessment will take approximately 1 hour each.

Focus group

Lastly, you will be invited to join a focus group discussion with the other participants of the study. The focus group is a group discussion about your experience and feelings (likes/dislikes) in taking part in the training. You will be free to share your views and opinions about the devices and training. This discussion will be audio-recorded and your identity will be kept confidential in all recordings. The focus group discussion will take approximately two hours.

As soon as we have enough numbers of participants (6-8 participants), we will contact you via phone to invite you to attend the focus group session at UTS Moore Park Campus.

ARE THEY ANY COSTS TO JOIN TO THE STUDY?

Joining in this study is free of charge. You will receive a $30 gift voucher as a monetary compensation if you join the focus group discussion

ARE THERE ANY RISKS? INCONVENIENCE?

There are no expected serious risks in joining the study. But like any other physiotherapy intervention, there is a chance of muscle soreness, fatigue, skin redness, joint strain and other exercise-related side effects which are normal responses of the body to exercise. With correct supervision from the trained therapist, all these side effects can be prevented or reduced. Moreover, possible emotional distress in answering some of the questions in the survey or interview is likely. If, you feel uncomfortable in answering any questions you have the choice not to answer.

If you experience any physical injuries, the therapist will refer you to your GP. If you experience emotional distress, as a result of the study, you will be referred to the UTS Psychology clinic or to your GP.

DO I HAVE TO SAY YES?

Participation in this study is voluntary. It is completely up to you whether or not you decide to take part.

WHAT WILL HAPPEN IF I SAY NO?

If you decide not to participate, it will not affect your relationship with the researchers or the University of Technology Sydney. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason, by contacting Mr. Esminio L. Rivera II.

If in case you have withdrawn from the study, please take note that all information you provided from all the phases of the study will be erased from our database (for a soft copy) and will be destroyed (hard copies like questionnaires)

CONFIDENTIALITY

By signing the consent form you, consent to the research team collecting and using your personal information in the research project. All this information will be treated confidentially. Only the investigator and the principal supervisor of the study will have access to the information you provided. Furthermore, during the voice recorded focus group your identity will be protected by making sure that your name or any details about you will not be cited. If in case, it will be cited, that part of the recording will be deleted.

Your information will only be used for this research project, and it will only be disclosed with your permission, except as required by law.

OTHER INFORMATION THAT YOU MUST KNOW

- There will be a quiet room for you to rest in case you feel tired because of the training.
- The training will be held on the second floor of UTS Moorepark Campus. There is a lift in the main entrance that you can use.
- A wheelchair will be provided for locomotion if you need, but please bring your own assistive device (e.g., cane, walking frame, and wheelchair)
- If you need a parking space or any other equipment, please contact Esminio (contact details below) before your visit. But please be aware that the parking space and the other equipment will depend on availability.
- If you are undergoing exercise therapy or rehabilitation, researchers of this study will contact your current therapist and/or your previous therapist (if needed) to confirm that the training protocol in the study will not interfere with your current treatment.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?

If you have concerns about the research that you think my supervisor or I can help you with, please feel free to contact one of the following:

Esminio L. Rivera II
Research Student
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Dr. Camila Quel De Oliveira
Principal Supervisor
Email: Camila.QuelDeOliveira@uts.edu.au

You will be given a copy of this form TO keep.

NOTE:

This study has been approved by the University of Technology Sydney Human Research Ethics. If you have any concerns or complaints about any aspect of the conduct of this research, please contact the Ethics Secretariat on ph.: +61 2 9514 2478 or email: Research.Ethics@uts.edu.au], and quote the UTS HREC reference number Committee [UTS HREC REF NO. ETH 18-3022]. Any matter raised will be treated confidentially, investigated and you will be informed of the outcome.