Title	Understanding the efficacy of the robotic rehabilitation of chronic stroke patients: pilot testing
IRB Institution	University at Buffalo
IRB Approval period	12/6/21-12/5/22

Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

"Adult Consent to Participate in a Research Study"

Title of research study: Understanding the efficacy of the robotic rehabilitation of chronic stroke patients: pilot testing

Version Date: 12.29.2021

Investigator: Nikhil Tej Kantu (Faculty Advisor: Jiyeon Kang)

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are chronic stroke patients over 18 years old.

Chronic Stroke refers to the period of recovery that takes place at least six months after the initial stroke event. Stroke patients who requires at least six months to recover are our target participants for this study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to understand whether robotic therapy can train activities of daily living tasks for chronic stroke patients. You are involved in a feasibility study to prove the efficacy of the robotic device with different force feedback (assistive and resistive force) and other feedback such as VR (virtual reality). We will collect movement data from a motion capture system and sEMG sensors that measure muscle activity to monitor the effect of a robotic rehabilitation device, named Spherical Parallel Instrument for Daily Living Emulation (SPINDLE). You will use a robotic therapy device to practice activities during daily living. This pilot study will be used to understand the effect of SPINDLE to translate the device as a home-based training for chronic stroke patients.

How long will the research last and what will I need to do?

We expect that you will be in this research study for a maximum of four hours.

You will be asked to wear reflective markers and sensors to measure your motion and muscle activation. You will perform repetitive activities of daily living tasks like drinking water, turning the doorknob, etc.

with or without the robotic device. If you are selected as the virtual reality group, you will wear an additional head-mounted device to perform activities of daily living tasks in virtual reality.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There won't be any significant risk in this study. The participant may feel fatigued from the repeated activities of daily living tasks with and without the robotic device. Breaks will be provided between sessions and based on the need of the participant. More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. Your alternative to participating in this research study is not to participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-645-6063 or jiyeonk@buffalo.edu. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 40 people here will be in this research study

What happens if I say yes, I want to be in this research?

If you agree to take part in the study, our research team will contact you by email or phone to set up an appointment. You will visit AWEAR Laboratory in Furnas Hall Room 809 at the University at Buffalo's North Campus or BGMC or UBMD Neurology clinic. We will ask you to wear comfortable clothing, which won't affect your natural movement. Once we start the experiment, reflective markers and sEMG sensors (Delsys Trigno surface electromyography) will be placed in various locations on your skin,

including the head, neck, shoulders, arms, torso, and a few on the lower body. These are non-invasive detectors attached with double-sided tape, used by the technology in the lab to detect motion and muscle activity. You will be performing multiple different activities of daily living tasks with or without the robotic device. There will be instructions on the computer monitor demonstrating the start and end posture of each task. The robotic and control group will be assigned randomly. The training will include similar to screwing in a lightbulb, using a screwdriver to screw in a screw, opening and closing a jar cap, pouring water from a pitcher, flipping a book, and Pouring water from a cup. If you are assigned as the virtual reality group, you will wear a head-mounted virtual reality system for visual feedback. Each task will be performed 10 times by you. If you need a break from performing these tasks, a 5-minute break will be given. The devices that will be used by you will be the everyday objects that would be used when performing these tasks, such as a pitcher, screwdriver, cup, and book. The devices used by the test administrator during this test will be the Vicon motion capture system, and Delsys EMGworks. Each activity of daily living task will take no longer than 20 minutes to perform and record, and the length of the visit should be no longer than 3 hours. Throughout the test, you will only be interacting with the test administrator. Once the test is complete, there is no need for a follow up with you once they leave the facility, but you may be contacted for future research.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me? (Detailed Risks)

The electrodes will be attached to the skin, which can cause mild skin irritation. Also, the virtual headset may cause some discomfort such as motion sickness, nausea, or other discomforts, while viewing virtual reality content. Once you express discomfort, we will stop the experiment and remove the virtual reality headset. You may feel fatigued from continued training with the force from the robotic device. The fatigued and irritation are temporary, would not last for a long time period.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the FDA, and other representatives of this organization.

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure. However, complete confidentiality cannot be promised. Despite all our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your data will be assigned a code number. All collected sensor data will be identified by this code and will be stored on a secured endpoint. Access will only be available to those working on the project. Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Audio/video recording or photography

As part of the research study, we seek your permission to take pictures and short clips of you. The recording(s) will be used for analysis and as a possible dissemination tool to those who are not members of our research team. Before disclosing your recording for educational or academic purposes, your face or personal identifiers will be removed from recordings or pictures. Pictures or videos will be stored on a secured endpoint (computer/laptop) together with the other digital data for at least 3 years in a folder

regarding this project, and will only be accessible to those working on the project. This study does not include any type of compensation for your participation. You do not have to agree to be recorded in order to participate in the main part of the study. If you sign in *option 1*, we will record your trials during the experiment for scientific and educational audiences for research and instructional purposes. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission. If you sign in *option 2*, we will record your trials during the experiment but do now allow the video tapes and pictures shown to scientific and educational audience. If you do not agree to record your trials, please select *option 3*.

Please select one of these options (Your initial):

___ Option 1: I consent to allow portions of the videotape and pictures of me to be shown to scientific and educational audiences for research and instructional purposes only. I understand that no identifying information beyond that contained in the tape will be provided in such sessions. I understand that these videos will be kept in a safe location.

___ Option 2: I consent to be audio/video recorded, but do now allow the videotape and pictures of me to be shown to scientific and educational audiences for research and instructional purposes only. I understand that these videos will be kept in a safe location.

___ Option 3: I do not consent to be audio/video recorded.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	