Title	Surveying stroke patient's current therapy and interest in robotic rehabilitation device
IRB Institution	University at Buffalo
IRB Approval period	12/8/21-12/7/22
Note	Version Date appears as 6.23.2021 because the initial approval date was 12/8/2020. There were few modifications in the study team members, age is changed from over 21 to over 18 and acute stroke is changed to stroke.

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: Surveying stroke patient's current therapy and interest in robotic rehabilitation device

Version Date: 6.23. 2021

Investigator: Jiyeon Kang, Amit Kandel, Saleem Ghazala

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 had an ischemic stroke within two months and are having difficulties performing activities during daily living such as drinking water, turning a door knob, etc. Individuals with pregnancy, other neurological disorders than stroke, or hemorrhagic stroke will be excluded from this study. Also, individuals with difficulties to read and understand the questionnaires are also excluded from this study. To participate in this study, individuals must be over 18 years old.

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 y
- 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 investigate the interest of individuals with recent stroke in robotic therapy. We will introduce a novel robotic platform to train ADLs of stroke patients. We will examine the usability of this device as a home trainer for training rotational hand manipulation tasks such as opening a pickle jar, turning a key, and missing a pot with a ladle, etc. The device will especially target stroke patients with ischemic stroke to enhance the performance of ADL. Also, we will examine the frequency and dosage of the current therapy, followed by the satisfaction of the current therapy. Your participation will contribute to the development of a new therapy method using a robotic device for home-based training.

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

We expect that you will be in this research study for about twenty minutes. The survey is divided by part A and part B. You will be asked to answer the questionnaire by making an x mark on the survey sheet. For part B of the survey, a video will be shown to you, which demonstrates a robotic upper limb

therapy to enhance the performance of activities during daily living. After watching the video, you will answer the part B of the questionnaire.

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 reading and answering the questionnaires. If you need, breaks will be provided between the questionnaires. 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 your 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 to not 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 __300___ people will be in this research study out of _ 795,0000 U.S. individuals with stroke for every year.

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 provide a consent form. You will read and sign on the consent form to participate in the study. Then, a questionnaire will be provided to you to fill out. You will start with the questionnaire section A. After section A, a video demonstrating rehabilitation

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robot will be shown to complete the questionnaire section B. You are allowed to ask questions before, during, and after answering the questionnaires.

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

You can leave the research at any time.

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

The minimal risk is to invoke frustration by reading and understanding the questionnaires. Some participants may feel boredom by answering the questionnaires.

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 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 name will be assigned a code number. The file that links your name to the code number will be kept in a locked file cabinet and only the PIs will have access to the file. All collected 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.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

__√__ Information from your full medical records: onset timing of the stroke, type of the stroke, age, sex

B. Who is authorized to create or provide this information for research use?

___√___ KALEIDA Health, Buffalo NY
_____ ECMC Healthcare Network, Buffalo NY
___√___ UBMD Clinical Practice Plan(s)
(identify):_____Neurology_____
_____ University at Buffalo School of Dental Medicine

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_____ Principal Investigator or designee
____ Other(s) (identify):_ _____

C. Who is authorized to receive the information from the information providers identified in (B)?

__√__ Principal Investigator or designee
__√___ Other(s) (identify):_____ Stroke team at BGMC and UBMD Neurology Clinics

D. With whom may your protected health information be shared?

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

__√___ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):
Jiyeon Kang PhD
email: jiyeonk@buffalo.edu
phone: 716-645-6063
address: Furnas Hall 1011 Buffalo, NY 14260-4200)

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

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	