Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: Wearable Sensor Platform to Monitor Stroke Recovery: A Clinical Exploratory Trial

Investigator: Arun Jayaraman, PT, PhD

Supported By: This research is supported by The Shirley Ryan AbilityLab

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have a had a stroke, and are currently undergoing rehabilitation in a hospital setting. Or, you may be asked to be a part of a healthy "control" group without any known significant health problems.

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.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can contact the Primary Investigator, Arun Jayaraman, at (312) 238-6875 or the lab manager, Lori McGee-Koch, at (312) 238-2091 during business hours Monday to Friday, 9:00 a.m. to 5:00 p.m.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- 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 have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why is this research being done?

The purpose of this study is to test body-worn sensor technology, that can help clinicians and therapists track how well someone is recovering from a stroke while they are going through rehabilitation in a hospital. The ability to continuously monitor how well someone is functioning and moving with these sensors may help to guide the rehabilitation process to make it more effective for patients.

You should not participate in this study if you are under the age of 18, if you are pregnant, or have any powered, implanted cardiac devices for monitoring or supporting heart function (i.e. pacemaker, defibrillator, or LVAD)

How long will the research last?

We expect that you will participate in this research study during your inpatient stay at the Shirley Ryan AbilityLab. If you are a member of the healthy "control" group, you will be involved in up to 3 laboratory visits expected to last 2-3 hours.

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How many people will be studied?
We expect about 100 people who have experienced a stroke will be in this research study, as well as about 55 people who are a part of the control group.

What happens if I say "*Yes, I want to be in this research*"?
If you are in the stroke group and consent to participate, then you will undergo four different types of assessments while you are a patient here, while wearing body-worn sensors. The four assessments will be clinical, swallowing/speech, exercise, and sleep/rest. Each of these assessments will be performed a minimum of three times, including: (1) at admission, (2) at treatment midpoint, and (3) at discharge. You may undergo additional assessments, for a maximum of five times for clinical assessments and a maximum of ten times for exercise, swallowing/speech, and sleep/rest.

If you are in the control group and consent to participate, then you will undergo three different types of assessments while wearing the body-worn sensors during up to three laboratory visits. These assessments will be clinical, swallowing/speech, and exercise assessments.

The sensors will be placed on the skin using adhesive stickers that minimize friction, with additional support of medical dressings as needed. All clinical and exercise assessments will be performed by a licensed physical therapist or occupational therapist. All swallowing and sleep/rest assessments will be performed by a clinician or research staff. You will be given rest breaks as needed between tests to minimize fatigue. Therapist assistance and body-weight support will be provided as needed.

1. Clinical Assessment:
For the Stroke group, sensors will be worn with various common clinical tests that will be performed. These include:

1. Modified Ashworth Scale (MAS)
2. 10-Meter Walk Test (10MWT)
3. 6-Minute Walk Test with or without VO2 analysis (6MWT)
4. Berg Balance Scale (BBS)
5. Functional Independence Measure (FIM)
6. Timed Up and Go (TUG)
7. Manual Muscle Test (MMT)
8. Action Research Arm Test (ARAT)

For the Control group, sensors will be worn with common clinical tests, including:

1. Modified Ashworth Scale (MAS)
2. 10-Meter Walk Test (10MWT)
3. 6-Minute Walk Test with VO2 Analysis (6MWT)
4. Berg Balance Scale (BBS)
5. Timed Up and Go (TUG)
6. Manual Muscle Test (MMT)
7. Gait analysis using GaitRite: self-selected and fast walking speeds (3 times each.)

- **Modified Ashworth Scale (MAS):** The MAS is a 6-point scale used to measure severity of muscle stiffness or tightness by testing resistance to stretch of your muscles around a joint

with varying degrees of speed. You will be asked to lay down and allow the therapist to move your limbs and assess for stiffness or tightness.

- **10-Meter Walk Test (10MWT):** The 10MWT measures the amount of time it takes to walk 10 meters. Time will be recorded using a stopwatch and recorded to the one hundredth of a second (ex: 2.15 sec). The test will be recorded 3 times at your normal self-selected pace and 3 times at a faster pace, with adequate rest in between. Results will be averaged from 3 trials.
- **6-Minute Walk Test with VO2 analysis (6MWT):** The 6MWT measures the distance a subject can walk indoors on a flat, hard surface in a period of 6 minutes, using assistive devices, as necessary. You are allowed to take rest breaks, however a timer will continue to run. A physical therapist will walk with you to ensure safety and assist as needed. A researcher will measure how many feet you walk during the 6-minute timeframe. You will also wear a mask over your mouth and nose during the test, which will be attached to a small box worn over your shoulder. You will breathe through this mask so that the amount of oxygen you use during the test can be measured.
- **Berg Balance Scale (BBS):** The BBS is a 14-item test. It measures how well you can balance while performing movements in sitting and standing (such as sitting, standing, transitioning from sitting to standing, standing on one foot, retrieving an object from the floor.) A physical therapist will ensure your safety and assist as needed during the test.
- **Timed Up and Go (TUG):** The TUG is a timed test that involves the participant rising from a chair, walking three meters, turning around, walking back to the chair, and sitting down.
- **Functional Independence Measure (FIM):** The FIM is an 18-item test (13 motor tasks, 5 cognitive tasks.) It is used to determine how much assistance you need to perform certain activities of daily living. Items include eating, grooming, bathing, dressing, toileting, bladder/bowel management, transfers, locomotion and stairs, comprehension, expression, social interaction, problem solving, and memory.
- **Manual Muscle Test (MMT):** The MMT is a standardized assessment to measure muscle strength. The therapist will use one hand to apply resistance or activate the muscle or tendon for contraction while the other hand stabilizes the body part being tested. The test will be repeated on all muscle groups required.
- **Action Research Arm Test (ARAT):** The ARAT is a 19-item test. It is used to test arm function and is divided into four subtests: grasp, grip, pinch, and gross movement. You will be asked to pick up various items (wooden block, ball, stone, tube, marble, ball bearing) and will be scored on your ability to do so.
- **Gait analysis:** You will be asked to walk approximately 13 feet on top of a mat that has sensors inside of it. The sensors in the mat will that generate a picture of your foot steps on a computer. You may use your assistive device while walking. A physical therapist will walk with you to ensure your safety and assist as needed during the test.

2. Swallowing/Speech Assessment:

If you are in the the Stroke group, you will wear the sensor(s) during your speech and language therapy. You will also wear the sensor(s) during eating to capture swallowing, throat clearing, coughing, wheezing, or gurgling noises. In addition, you will wear the sensor(s) during your

videfluoroscopic swallow assessment if this test is scheduled as part of your standard of care treatment (i.e., determined by your physician and clinican-prescribed treatment plan)

If you are in the Control group, you will wear the sensor(s) during a brief conversation and during eating to capture swallowing, throat clearing, coughing, wheezing, or gurgling noises.
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3. Exercise Assessment:
For the Stroke group, the Exercise Assessment will monitor patients during various types of scheduled therapy, including occupational therapy (OT), gait therapy (i.e. treadmill training and over ground walking), and other customary exercises undertaken during therapy. Sensors will measure vital signs, sweat, as well as movement and muscle activity in the upper and lower limbs.

For the Control group, the Exercise Assessment will involve walking on a treadmill for up to 45 minuteswalking up and down stairs, and cycling (lower limbs). Stair and cycling activities will be performed for 10 minutes. All activities will be perfomed at a comfortable pace.

4. Sleep/Rest Assessment:
For the Stroke group, the Sleep/Rest Assessment will monitor patients during overnight sleep and during wakeful rest in their rooms. Sensors will measure vital signs and movement in the upper and lower limbs.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to: participate in all scheduled sessions and notify the research team of any changes in your health.

What happens if I do not want to be in this research?
You are not required to be in this research. If you chose not to be involved, then you will continue to undergo your regular rehabilitation care while in the hospital.

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time and it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Information collected prior to the study discontinuation by a participant may still be used by the research team.

What are the risks of being in this study? Is there any way being in this study could be bad for me?
There is a risk of muscle soreness due to increased physical activity during testing sessions. All subjects will work with trained researchers and clinicians. Adequate rest will be given and subjects will be monitored by for verbal or visual signs of fatigue or discomfort.

There is a risk of falling during clinical and exercise assessments. The risk of falling will be reduced by having each participant supervised during training and testing by a clinician

or researcher trained in all testing procedures. During these assessments, the participant will use a gait belt for safety. The risk is similar to that during any clinical inpatient/outpatient therapy session.

There is a risk of irritation to the skin from wearing the sensors. This risk will be reduced by minimized by excluding people who have a known allergy and discontinued use if skin irritation occurs.

Risks associated with swallowing and speech activities are the same as those associated with routine standard of care. You may experience difficulties swallowing or choking during mealtimes. There may also be frustration if speech tasks are deemed too difficult. Trained therapists will be present for all swallow/speech tasks, and you will be given frequent rest breaks as needed.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

There will likely be no direct benefit by participating in this research study. The long-term goal of this research is to improve the ability to measure symptoms of stroke and look at the impact of new therapeutic interventions during the inpatient stay. This benefit could lead to better treatments in the future.

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 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 institution.

If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include a medical event or complication that may alter the inclusion/exclusion criteria, or which limits the patient from safely completing the remainder of the study, or at the discretion of the PI.

What else do I need to know?

The data collected in this study includes the biometric data collected by the sensor devices, as well as information about your height, weight, age and gender, and any information you and the

study staff share via the MC10 Investigator App, Investigator Portal or Link App. This data will be shared with MC10, Inc. (the manufacturer of the sensors and the associated software). Shirley Ryan AbilityLab and MC10, Inc. will take appropriate measures to protect your information. MC10, Inc. may use aggregated data to answer additional scientific questions, for product development purposes, to market or promote its products and services, or it may sell the data to interested audiences. MC10 may keep the data indefinitely.

Please be adviced that these sensors have not been tested on the following groups: pregnant women, individuals with powered, implanted cardiac devices for monitoring or supporting heart function (i.e. pacemaker, defibrillator, or LVAD), and individuals below 18 years of age.

MC10 has asked that you do not provide it with any information that could be used to identify you through their sensor devices, their website, or their other services.

This data will also be accessible to the John Rogers research group.
If you become ill or get injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

You will be paid $40 for each session that you attend in the healthy control group. You will be paid $200 for your participation in the inpatient group. These funds are provided to help support you with time and travel associated with your participation.

The Shirley Ryan AbilityLab will issue you a ClinCard, which is a specially designed debit card for clinical research. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card. The funds will be available within 1 day after being loaded and can be used at your discretion.

You will be issued one card for the duration of your participation. If your card is lost or stolen, please call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

Fees are incurred if used at an ATM (fees vary by location). However, if the card is used for in-store or online purchases via credit or debit, there are no associated fees and no expiration date.

Please be advised: Inactivity on the card for more than 3 months will incur a monthly fee. However, as long as there is activity on the card within 3 months (funds are added or a transaction is completed), the month period will reset and no monthly fee will be assessed.

If you do incur a monthly fee, please contact Greenphire Support at the number on the back of your card and they will reverse the fee. See "Tips for Using the Attached ClinCard" for more information.

The Finance Department at the Shirley Ryan AbilityLab will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service

(IRS). An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

You may be given access to new inventions that are being developed by the investigator, the study sponsor, or other people involved in the study. Certain laws can make it harder to obtain legal protection for a new invention shared with a study participant, unless the study participant agrees to keep information about the invention confidential. You agree to keep confidential information you may receive about new inventions, such as new drugs, new devices, or new methods.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates), the Northwestern University Institutional Review Board Office and Office for Research Integrity, the US Office of Research Integrity, the US Office for Human Research Protections, the US Food and Drug Administration will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is necessary for review by such parties or is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office].

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study).
- Clinical affiliates, including but not limited the Shirley Ryan AbilityLab, Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly.

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Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Arun Jayaraman
Institution: Shirley Ryan AbilityLab
Department: Center for Bionic Medicine
Address: 355 E Erie St, #1401, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Please initial one of the following to indicate your choice:

_____ (initial) I **agree** to have photographs and videos taken to aid with data analysis or for use in education, scientific publications or presentations **with my face included.**

_____ (initial) I **agree** to have photographs and videos taken to aid with data analysis or for use in education, scientific publications or presentations **without my face included.**

_____ (initial) I **do not agree** to have photographs and videos during my study participation.

_____(initial) I **agree** the researcher may contact me in the future to see whether I am interested in participating in other research studies.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

If participant is physically unable to sign, please have a witness sign below:

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process