STU#: 00213155

Permission to Take Part in a Human Research Study

Title of Research Study: Comparison of two high-intensity gait training interventions on contraversive pushing behaviors in individuals poststroke

Investigator: Arun Jayaraman, PT, PhD

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

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

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 recently had a stroke and are currently undergoing rehabilitation in a hospital setting.

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 compare the effects of two walking interventions on balance and posture poststroke. The two interventions are walking on the treadmill and walking in the EksoNR exoskeleton. The EksoNR exoskeleton is a robotic device that provides assistance at the trunk and both legs at the hips, knees, and ankles during walking. It is approved by the US Food and Drug Administration (FDA) for use in individuals poststroke.

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

We expect that you will participate in this research study during the length of your inpatient stay at the Shirley Ryan AbilityLab. These sessions will be in addition to your normally scheduled therapy.

You will be asked to participate in 3 training sessions per week for the duration of your inpatient stay. There will also be screening, baseline, and weekly assessment sessions to collect data regarding your walking, balance, and physical function.

More detailed information about the study procedures can be found under the section **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?

The potential risks of participation in this study include:

- The risk of falling

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- Pressure or friction from where the harness or exoskeleton touches you
- The risk of muscle soreness
- The risk of a device error
- The risk of loss of confidentiality

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 any way?

We cannot promise any benefits to you or others from your taking part in this research. However, other research has shown that walking training may lead to improvements in balance, mobility, and function.There is the potential for you to experience the same benefits in this study.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team: Kate Enzler, PT at (312)238-2941 or Alyssa Jones, PT at (312)238-6837.

Arun Jayaraman, PT, PhD is the person in charge of this research study. You can call him at (312)238-6875 during normal business hours Monday-Friday.

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.

How many people will be studied?

We expect about 30 people who have experienced a stroke will be in this research study.

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

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This research study will occur at Shirley Ryan Abilitylab flapship hospital in the Legs + Walking Lab. You will participate in the following:

- Screening:

  First, an initial screen will be completed to ensure you are interested and meet eligibility criteria. Once you confirm your interest and provide us with your permission, we will obtain medical clearance from your physician prior to any walking training. Then, you will be assigned to one of two groups: ○ Group 1: All training sessions will be completed using a harness on the Woodway treadmill with some sessions including additional walking on the ground. ○ Group 2: All training sessions will be completed using the EksoNR exoskeleton device with some sessions including additional walking on the ground.

- Training Sessions:
  All training sessions will be scheduled during your usual physical therapy time. This study will not interfere with your routine therapy schedule. You will participate in up to 24 walking sessions, 3 times per week for the duration of your inpatient stay or up to 8 weeks. Each session will last from 60 to 90 minutes. During each session, you and your physical therapist will work towards maximizing the amout of time spent walking and the number of steps taken.

- Clinical Assessment Sessions:
  At the beginning of the study and weekly, a licensed physical therapist will track you performance by guiding you through assessments that measure your walking, balance, strength, and mobility. You will be provided physical assistance and rest breaks as needed. Clinical assessment sessions may last 60 to 90 minutes. Please see below for further details of the clinical assessments.

Clinical Assessments:

- Scale for Contraversive Pushing (SCP): The SCP assesses your posture and balance in sitting and in standing. You will be asked to sit and stand in place. Then, the therapist will help you correct your posture in sitting and standing.
- Burke Lateropulsion Scale (BLS): The BLS assesses your posture and balance in five different positions: rolling while lying down, sitting, standing, transferring between the wheelchair and the mat table, and walking. The therapist will passively roll you when lying down, help you correct your posture in sitting and standing, assist with the transfer, and help you walk.
- 10 Meter Walk Test (10MWT): The 10MWT assesses walking speed by measuring the amount of time it takes to walk 10 meters. The test will be recorded 2 times at your normal self-selected pace and 2 times at a faster pace with adequate rest in between. Results will be averaged from the trials. This will be tested overground using the appropriate assistance from the physical therapist as well as the appropriate assistive device and bracing.
- 6 Minute Walk Test (6MWT): The 6MWT measures the distance you can walk indoors on a flat, hard surface in a period of 6 minutes to measure your endurance. This will be tested overground using the appropriate assistance from the physical

therapist as well as the appropriate assistive device and bracing. You are allowed to take rest breaks; however, a timer will continue to run.

- Berg Balance Scale (BBS): The BBS is a 14-item test to assess your balance and fall risk. Activities include sitting, standing, balance during transfers, reaching, turning, eyes open, and eyes closed.
- Function in Sitting Test (FIST): The FIST is a 14-item test to assess sitting balance at the edge of the mat table. Activities include reaching, picking up an object, scooting, and sitting with eyes closed.
- Functional Independence Measure (FIM): The FIM evaluates how much assistance is needed for mobility tasks, including moving around in bed, moving between the wheelchair and mat/bed, walking, performing stairs, and moving in the wheelchair.
- Quality Indicators (QI): This is a measure to track changes in function for all mobility tasks, including moving around in bed, moving between the wheelchair and mat/bed, walking, performing stairs, and moving in the wheelchair.
- Manual Muscle Testing (MMT): This is a test to determine how strong your muscles are in your legs. You will be asked to hold a position while a trained therapist applies resistance.
- Passive Range of Motion (PROM): We will measure the flexibility of the muscles in your legs.
- Modified Ashworth Scale (MAS): This is a test to determine if there is any resistance to movement or spasticity in your legs.

Wearable sensors worn during training sessions:

- ActiGraph activity monitor: The ActiGraph activity monitor is a wearable sensor worn to track the number of steps and calories used during daily activity.
- Polar heart rate monitor: The Polar heart rate monitor will continuously track your heart rate during each session.

The research team may take photos or videos of you during evaluation or treatment sessions to aid with data analysis or to use in scholarly presentations or publications. These photos and videos are optional and will only be taken if you provide your consent.

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 screening, training, and evaluation sessions
- Be on time to training sessions
- Communicate with research personnel if you have any questions, pain or injuries.

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 decide to leave the research, contact the investigator so that the investigator can remove you from the research study.

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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.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

If you agree, this data will be handled the same as research data.

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

This research may hurt you in the following ways:

- Risk of falling: This could be caused by a loss of balance during walking training. The risk of falling may result in an injury, ranging from no injury to a major injury. This risk will be minimized by having experienced physical therapists conduct the sessions as well as using safety accessories such as a gait belt or harness.

- Risk of skin breakdown: Pressure or friction from where the harness or exoskeleton touches you may lead to skin breakdown, pain, bruising, or unusual swelling. This will be minimized by physical therapists performing skin checks at each training session. In addition, they will ask for your feedback regarding discomfort and pain. Adjustments to the sizing, placement of additional padding, and amount of device assistance will be made in order to address any of these concerns.

- Risk of joint pain: Discomfort or pain of your joints will be minimized by having physical therapists monitor for pain at joints throughout training sessions and adjust the amount of assistance the device provides in order to address concerns.

- Risk of muscle soreness: Physical therapists will minimize your muscle soreness or fatigue during sessions by offering rest breaks as requested/needed.

- Risk of device malfunction: The treadmill or exoskeleton device could malfunction. All activities will be performed with close supervision from trained physical therapists to monitor device function during use.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

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.

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Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include: improved walking and balance following the training sessions. Possible benefits to others include: information from this study will assist therapists in future treatment for individuals poststroke.

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, Shirley Ryan AbilityLab, 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), and the 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you become ill or are 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.

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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 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:

- 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 devices

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities 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.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- 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.

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- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- 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,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

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: Max Nader Laboratory for Rehabilitation Technologies and Outcomes
Address: 355 E. Erie Street, Room 11-1402, Chicago, IL

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.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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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.

I agree	I disagree	
_____	_____	The researcher may photograph, audio, or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may photograph, audio, or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

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

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

Your signature documents your permission for the named participant to take part in this research.

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Permission to Take Part in a Human Research Study

Printed Name of Participant	
Signature of Legally Authorized Representative	Date
Printed Name of Legally Authorized Representative	Date
Signature of Person Obtaining Consent	Date
Printed Name of Person Obtaining Consent	Date