

Study Title: Safety, Reliability, and Efficacy of the Harmony SHR™ Upper Extremity Robotic Rehabilitation System in the Inpatient Rehabilitation Setting for Patients with Acute Stroke

NCT Number: NCT05251077

Document: Informed Consent Form

IRB approval date: 10-31-2022

Permission to Take Part in a Human Research Study

Title of Research Study: *Safety, Reliability, and Efficacy of the Harmony SHR™ Upper Extremity Robotic Rehabilitation System in the Inpatient Rehabilitation Setting for Individuals with Acute Stroke*

Investigator: *Arun Jayaraman, PT, PhD*

Supported By: This research is supported by Harmonic Bionics.

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 have had a stroke that has affected your upper extremity mobility and you are currently admitted as an inpatient in the rehabilitation 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 study is to assess the safety, feasibility, and efficacy of the use of the Harmony SHR™ upper extremity robotic rehabilitation system for persons with impaired functional use of one or both upper extremities due to acute stroke.

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

We expect that you will be in this research study for up to 24 sessions lasting up to one hour each within the duration of your inpatient rehabilitation hospital stay.

You will be asked to participate in up to 24 sessions using the Harmony SHR™ device with a trained researcher. In addition, you will complete a baseline testing session prior to the intervention sessions and an endpoint testing session after you have completed the intervention sessions.

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?

Possible risks from study participation may include, but are not limited to the following:

- Skin Irritation
- Worsening of Spasticity
- Joint Subluxation or Worsening of Subluxation

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- Transient Numbness or Tingling/Nerve Impingement
- Dislodged Medical Devices
- Muscle Soreness
- Device Malfunction
- 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, possible benefits include improved passive and/or active range of motion, improved strength, improved motor control, and/or reduced pain.

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: Kelly Breen, OT at 312-238-1350

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 40 people here will be in this research study out of 40 people in the entire study nationally.

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

You will be randomized into one of 2 groups:

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Group 1: Intervention group

Group 2: Control group

Randomization means you will be randomly assigned to a treatment group based on chance, like flipping a coin. Neither you nor the researcher chooses your assigned group. You will have equal chance of being in either group.

An additional group (Optimization group) of up to 10 participants will be enrolled with the goal of identifying optimal device application in the acute stroke population. The purpose of this group is to 1) train study staff prior to randomization and 2) ensure adequate inclusion/exclusion criteria for this study. This group will not be randomized. If you are allocated to this group, you will participate in the same treatment as the intervention group.

If you are in the intervention group, you will participate in the following:

1. **Screening Procedures:** An initial screen will be completed to ensure you are interested and meet eligibility criteria. We will also obtain medical clearance from your physician prior to any testing and device training.

Following screening procedures, confirmation of eligibility, and signing of the consent form, you will be scheduled for baseline and follow up testing sessions and up to 24 intervention sessions.

2. **Baseline Testing:**

- **You will complete:**
 - Medical intake questionnaire (age, diagnosis, past medical history, hand dominance, medications)
 - Manual muscle test (MMT)
 - Action Research Arm Test (ARAT)
 - Fugl-Meyer Assessment (FMA)
 - Modified Ashworth Scale (MAS)
 - Shoulder pain assessment using either the visual analog scale or numeric pain rating scale.
- **Quality Indicator (QI) scores** related to your upper extremity mobility in addition to any of the listed or other outcome measures will be mined from your medical chart in the Cerner electronic medical record and recorded in your research file. In the event that the score is not found in your medical record, it will be performed by study staff.
- **Sizing and set up of the device:** This will involve obtaining your physical measurements as needed for proper fitting of the device:
- **Assessment of upper extremity range of motion supported by the device:** You will perform a series of active and passive motions while in the device:
 - Range of motion (ROM) supported by the device, weight support/gravity compensation, and bilateral movements.

3. **Intervention sessions:**

- After completion of baseline testing, you will be scheduled for up to 24 intervention sessions using the Harmony SHR™. Each session will last up to 60 minutes. You will be set up by research personnel with the device but activities to be performed with the device will be customized for you based on your level of

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ability. Activities will also consist of tabletop one handed and two handed tasks, including but not limited to:

- i. Brushing hair, lifting weighted can, opening/closing of activities of daily living (ADL) containers, cutting of simulated food, brushing teeth, and other ADLs which are task-specific in nature.
- All sessions will be completed by a trained researcher and/or licensed occupational therapist. You will be continuously monitored for fit and comfort of the device, including skin inspections at the beginning and end of each session as well as intermittent checks as needed throughout the session to assess any skin breakdown or irritation that may occur as a result of using the device. You will be permitted to stop the activity and rest at any time during the session.

4. Endpoint Testing:

- **You will complete the following outcome measures:**
 - MMT
 - ARAT
 - Fugl-Meyer
 - MAS
 - Shoulder pain assessment using the either the visual analog scale or numeric pain rating scale.
- **Quality Indicator (QI) scores** related to your upper extremity mobility in addition to any of the listed or other outcome measures will be mined from your medical chart in the Cerner electronic medical record and recorded in the your research file. In the event that the score is not found in your medical record, it will be performed by study staff.
- **Assessment of upper extremity range of motion supported by the device:** You will perform a series of active and passive motions while in the device:
 - Range of motion (ROM) supported by the device, weight support/gravity compensation, and bilateral movements.
- **You will be administered a questionnaire** comprised of questions related to your perspective on use and comfort of the device

If you are in the control group, you will participate in the following:

1. **Screening Procedures:** An initial screen will be completed to ensure you are interested and meet eligibility criteria. We will also obtain medical clearance from your physician prior to any testing and device training.

Following screening procedures, confirmation of eligibility, including fit in the device, and signing of the consent form, you will be scheduled for baseline and follow up testing sessions and up 24 interventions sessions.

2. Baseline Testing:

- **You will complete:**
 - Medical intake questionnaire (age, diagnosis, past medical history, hand dominance, medications)
 - Manual muscle test (MMT)
 - Action Research Arm Test (ARAT)
 - Fugl-Myer Assessment (FMA)
 - Modified Ashworth Scale (MAS)

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- Shoulder pain assessment using the either the visual analog scale or numeric pain rating scale.
- **Quality Indicator (QI) scores** related to your upper extremity mobility in addition to any of the listed or other outcome measures will be mined from your medical chart in the Cerner electronic medical record and recorded in the your research file. In the event that the score is not found in your medical record, it will be performed by study staff.

3. Intervention sessions:

- After completion of baseline testing, you will be scheduled for up to 24 intervention sessions of conventional occupational therapy. Each session will last up to 60 minutes. Activities you will perform will consist of tabletop one handed and two handed tasks, including but not limited to:
 - i. Brushing hair, lifting weighted can, opening/closing of activities of daily living (ADL) containers, cutting of simulated food, brushing teeth, and other ADLs which are task-specific in nature.
- All sessions will be completed by a trained researcher and/or licensed occupational therapist. You will be permitted to stop the activity and rest at any time during the session.

4. Endpoint Testing:

- **You will complete the following outcome measures:**
 - MMT
 - ARAT
 - Fugl-Myer
 - MAS
 - Shoulder pain assessment using the either the visual analog scale or numeric pain rating scale.
- **Quality Indicator (QI) scores** related to your upper extremity mobility in addition to any of the listed or other outcome measures will be mined from your medical chart in the Cerner electronic medical record and recorded in the your research file. In the event that the score is not found in your medical record, it will be performed by study staff.
- **You will be administered a questionnaire** comprised of questions related to your perspective on use and comfort of the device.

Your vital signs (blood pressure, heart rate, etc.) will be assessed as needed throughout baseline, intervention, and endpoint testing sessions. You will also be given rest breaks as needed throughout each session.

OUTCOME MEASURES:

Quality Indicator (QI): The QI evaluates how much assistance is needed for you to perform certain activities of daily living. Each item is scored ranging from total assistance to total independence. Items include eating, grooming, bathing, dressing, toileting, bladder/bowel management, transfers, locomotion and stairs, comprehension, etc.

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Action Research Arm Test (ARAT): The ARAT is a 19 item observational measure used to assess upper extremity performance (coordination, dexterity, and functioning) in stroke recovery, brain injury, and multiple sclerosis. Items comprising the ARAT are categorized into 4 subscales (grasp, grip, pinch, gross motor) and arranged in order of decreasing difficulty, with the most difficult task examined first, followed by the least difficult task. Task performance is rated on a 4-point scale, ranging from 0 (no movement) to 3 (movement performed normally).

Fugl-Meyer Assessment (FMA): The FMA is a stroke-specific, performance-based impairment index designed to assess motor functioning, balance, sensation, and joint functioning in patients with post-stroke hemiplegia. For the purposes of this study, only the upper extremity motor functioning domain will be assessed. This domain is comprised of assessing movement, coordination, and reflex action of the shoulder, elbow, forearm, wrist, and hand. Scoring is based on direct observation of performance and scale items are scored on the basis of ability to complete the item using a 3-point ordinal scale where 0 = cannot perform, 1 = performs partially, and 2 = performs fully.

Manual Muscle Testing (MMT): The purpose of this test is to evaluate the strength of your upper extremities by having you hold your arm in a position while the researcher applies manual resistance.

Modified Ashworth Scale (MAS): The MAS is a 6-point ordinal scale used to grade the amount of increased tone in individuals with neurological diagnoses. A score of 0 indicates no increase in tone while a score of 4 indicates rigidity. Tone is scored by passively moving the individual's limb and assessing the amount of resistance to movement felt by the examiner.

Visual Analog Scale or Numeric Pain Rating Scale: The 0-10 rating scale for pain is used to gain a subjective report of the intensity of a person's pain. Zero represents "no pain" and ten represents "the most intense pain imaginable".

Patient questionnaire: This questionnaire will ask for the your feedback regarding your perspective on use and comfort of the Harmony SHR during the training sessions. It will be completed at the post testing session.

Video recording and/or pictures may be taken of the participants during assessments and/or during the training sessions. These may be used to for presentations and training of other research personnel. All attempts will be made to ensure the images or videos used are devoid of any identifying information. Each participant may choose to limit if/how these items may be used, as indicated during their consent process.

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 testing 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:

- **Skin Irritation:** The wrist and upper arm accessories may cause skin irritation and have a remote likelihood of causing skin injury. This risk will be minimized by a thorough skin check performed by trained research personnel at each session as well as asking for participant feedback. Adjustments to sizing, placement of additional padding, and amount of device assistance will be done in order to address concerns.
- **Worsening of Spasticity:** Participants with spasticity might experience a transient or permanent worsening of spasticity.
- **Joint Subluxation or Worsening of Subluxation:** Due to the large range of motion of Harmony SHR, there is a rare possibility that patients may experience an onset of subluxation or worsening of existing subluxation upon use of the device.
- **Transient Numbness or Tingling/Nerve Impingement:** Though improbable, there is a likelihood of the participant being subject to transient numbness or tingling and/or nerve impingement in the event that the device is improperly set up.
- **Dislodged medical devices:** There is a remote likelihood that devices such as an ostomy pouch or feeding tube may become dislodged while using the device. Only trained research personnel will be initiating set up and use of the Harmony SHR to minimize these risks.
- **Muscle Soreness:** There is a risk of muscle soreness from exercises during the intervention sessions. Trained research personnel will be initiating testing and training sessions with simple activities, progressing to more dynamic, complex activities when it is clear to do so. Adequate rest periods will be provided as needed.
- **Device Malfunction:** The device itself could malfunction. All activities will be performed with close supervision from trained research personnel to monitor device function during use.
- **Risk of Loss of Confidentiality:** This risk will be minimized by not including personal identifying information on forms (subject will be assigned a research study number)

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 passive and/or active range of motion, improved strength, improved motor control, and/or reduced pain.

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 the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

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), and 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.

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 Principal Investigator.

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 have an injury or illness from the study device, taking the study drug, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of

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the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

If you agree to take part in this research study, we will pay you \$50 for the baseline session, \$50 for the endpoint session, and \$20 for each intervention session.

You will be paid \$50 for each evaluation session and \$20 for each intervention session that you attend. 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

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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) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

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.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, 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.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, 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,
- Harmonics Bionics, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

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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.

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, PT, PhD

Institution: Shirley Ryan AbilityLab

Department: Max Nader Laboratory for Rehabilitation Technologies and Outcomes

Address: 355 E. Erie Street, Room 11-1401, 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.

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 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 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

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Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent