The Effects of Incorporated Exoskeletal-Assisted Walking in SCI Acute Inpatient Rehabilitation
PI: Ann M. Spungen EdD
NCT04221373
Document Date: 5-10-2022

STUDY-19-00614 **Form Version Date: 05/21/2021**

STUDY INFORMATION:

Study Title: The Effects of Incorporated Exoskeletal-Assisted Walking in SCI Acute Inpatient Rehabilitation

Principal Investigator (Head Researcher): Ann M. Spungen, EdD

Physical Address: [redacted] Rehab Suite, New York, NY 10029

Mailing Address: [redacted] Rehab Suite, New York, NY 10029

Phone: 212-824-8370

SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to test the effect of early exoskeletal-assisted walking (EAW) training (combined into regular acute inpatient rehabilitation (AIR)) on improving functional recovery and reducing pain and inflammation. Powered exoskeletons are a technology that offer standing and walking for certain persons with spinal cord injury (SCI) who meet the using indication of the device and have been used in the chronic SCI population with positive benefits in ability to move, daily function (such as bathing and dressing), body composition (such as lean and fat tissue mass), and quality of life (QOL). Despite the potential for EAW to promote functional recovery and reduce secondary medical complications (such as urinary tract infections and pain), no reports exist on the use of exoskeletons in AIR.

If you choose to participate, you will be asked to randomly join into either the intervention group or the control group. If you are in the intervention group, you will receive walking training using an EksoGT™ powered exoskeleton included in your regular rehabilitation therapy. The EksoGT™ is one of FDA approved powered exoskeletons designed to help persons with SCI and stroke get back to walk. The walking training is about 20 to 30 minute per session, one session a day, equal or more than 3 sessions/days per week, from enrollment in the study to discharge from the acute inpatient rehabilitation. If you are in the control group, you will receive regular rehabilitation therapy during inpatient rehabilitation, which may have walking training without using an Ekso™ based on your therapist's decision. Even so, either group will have the same rehabilitation time per week, which are total 15 hours per week. The study will start from your enrollment in the study and end at your discharge from the acute inpatient rehabilitation. There are no extra costs and compensation associated with your participation.

The main risks to you if you choose to participate are that EAW training may cause you hypotension, falls, skin abrasion, muscle soreness, joint damage, other musculoskeletal injury, and/or autonomic dysreflexia (which may make you have a flushed feeling, pounding headache, and heavy sweating with dangerously high blood pressure and very low heartbeat because your autonomic nervous system overreacts to something below your damaged spinal cord). There are multiple mechanisms in place to minimize these risks.

Participating in this research will not benefit you. Instead of participating in this research, you may have the opportunity to join other existing EAW studies in the Center for the Medical Consequences of Spinal Cord Injury at James J. Peters Veterans Affairs Medical Center.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are over 18 years and have non-progressive SCI, and are eligible for walking training as part of your acute inpatient rehabilitation in the Mount Sinai Hospital.

Funds for conducting this research are provided by New York State Department of Health, Postdoctoral Fellowships in Spinal Cord Injury Research.

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.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last from enrollment in the study to discharge from the SCI acute inpatient unit at the Mount Sinai Hospital. The number of people expected to take part in this research study at the SCI acute inpatient unit at Mount Sinai Hospital is 40.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

During your stay in our acute inpatient rehabilitation unit, you will be randomly assigned into either the intervention group or the control group. The two groups (control and intervention) will have the same total amount of rehabilitation therapy time (total 15 hours of physical and occupational therapy per week from inpatient admission to discharge). The study treatment you get will be chosen by chance, like getting 1 to 4 when rolling a dice. Neither you nor the study doctor will choose what experimental study treatment you get. You will have *2/3* chance of being assigned to the intervention group and 1/3 chance of being assigned to the control group.

Intervention group: In the intervention group, you will receive EAW training provided with an EksoGT™ powered exoskeleton. The EksoGT™ is one of FDA approved powered exoskeletons designed to help persons with SCI and stroke get back to walk. You will still have the standard of care of acute inpatient rehabilitation at Mount Sinai Hospital with the exception that the EAW training will be included into the regular therapy time (total 15 hours of physical therapy (PT) and/or occupational therapy (OT) per week). The EAW training will be provided as determined by the clinical team from the earliest time you are identified to be able to safely stand, through discharge. The goal of EAW intervention is to complete 3 or more sessions of EAW training a week during the AIR period (after enrolling into the study until discharge). One EAW session is defined to have at least 20 minutes of up time in the device (based on data output from EksoGT™ device). EAW sessions will include device fitting, instruction for sit-to-stand and stand-to-sit maneuvers; balance and fall protection training; and walking on smooth indoor surfaces. The clinical team will determine the frequency, duration, and intensity of each EAW session based on your response to the previous session.

Control group: You will receive standard of care AIR which includes total 15 hours of PT and/or OT per week until you are discharged. This standard of care AIR may include bed mobility, balance, strength, gait, transfers, and wheelchair mobility training to improve your independence in activities of daily living, such as bathing, eating, dressing, grooming.

Several exams and questionnaires will be used to assess your condition after your enrollment (within 1-2 days) and before your discharge from AIR (±2 days). The reasons and number of adverse events and missing EAW sessions after the enrollment until discharge will be recorded. The number of EAW sessions and total steps, up and walk time you finish in the device will also be recorded.

Your motor function, which means some key muscle strength, will be assessed using International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) upper and lower limb motor scores. Your independence in performing daily activities will be assessed using Functional Independence Measure (FIM) and Spinal Cord Independence Measure (SCIM) scores evaluated by clinicians. FIM, SCIM, and ISNCSCI exams are part of the standard of care assessments at the Mount Sinai Hospital AIR program. Your will have these assessments performed at admission and discharge.

1) ISNCSCI exam is a neurological evaluation for sensation and muscle function, level of injury (means the lowest segment of spinal cord with normal sensation and muscles that can have active movement through the full range of motion against gravity on both sides of the body) and upper and lower extremity motor scores. ISNCSCI evaluations will be performed by a physician.
2) FIM is a tool with 18 items to assess your physical, mental and social function based on the level of assistance you need. The 18 items of the FIM are categorized into 6 areas, including self-care, sphincter control, transfers, locomotion, communication, and social cognition. The grading system is from 1 to 7 with 1 indicating total assistance needed and 7 indicating complete independence.
3) The SCIM is a clinical tool to evaluate the independence of performing activities of daily living (ADL) developed especially for people with SCI. The latest version of SCIM, version III and the self-report version, included 19 questions of daily activities with total score between 0 and 100. The questions can be divided into three subgroups: self-care, respiration and sphincter management, and mobility. If you need total assistance or dependence to perform an ADL task, you will receive a score of 0 for that task. A higher final score indicates more independence.
4) If you can walk without using a powered exoskeleton, a 10 meter walk test (10 MWT) and Walking Index for Spinal Cord Injury II (WISCI II) will be used to evaluate your walking ability (without using the exoskeleton) by a research team member or a clinician before and after training. In the 10 MWT, you will be asked to walk 10 meters (without the exoskeleton) at your fastest, comfortable pace. The time to cover this distance will be timed with a stopwatch. The 20-item WISCI-II provides a rank-order rating of the ability of a person with SCI to walk 10 meters in relation to severity of impairment. Ratings consider the amount of assistance and the types of assistive devices (e.g., leg braces) required to walk. Both the 10 MWT and WISCI II will be evaluated after enrollment (within 1-2 days) and before discharge from AIR (±2 days).

Your pain will be assessed using the International Spinal Cord Injury Basic Pain Data Set 2.0 (ISCIBPDS 2.0) and the Spinal Cord Injury Pain Instrument (SCIPI) which when completed will identify pain location, classification, and the average-of the 7-day pain intensity assessment.

5) ISCIBPDS 2.0 contains critical questions about clinically relevant information concerning SCI-related pain during the last 7 days, including pain intensity, the influence of pain on daily activities, mood, and sleep, pain location, and pain classification.
6) SCIPI is a tool used to classify pain after SCI using 7 questions. It can be easily used to identify the pain classifications, including neuropathic, nociceptive, neither or unknown.

In either group, your blood will be drawn in the study. A half tablespoon of blood will be drawn in a red top tube, two times (beginning of the study and before discharge) for a total of a full tablespoon of blood over the course of the full study for analyses of the inflammatory markers. The presence and degree of systemic inflammation will be determined by measuring the concentration of serum C-reactive protein (CRP). CRP is an acute phase protein which rises in response to inflammation. It is not specific to inflammation caused by SCI. CRP is routinely measured from patients clinically when it is important to assess the degree of inflammation is present.

Because this project involves the use of medications or a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

For Women:

Since you are participating in a research study that involves drugs or experimental treatment with potential risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. You should not participate if you are breastfeeding.

Recommended methods of birth control are:

- The consistent use of an approved hormonal birth control (pill/patches, rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual intercourse) or
- Sterilization

Hormonal birth control, implants, and injections are only considered effective if used properly and started at least one month before you begin the study, continuing throughout the study and for one month after the end of the study. You should ask your study doctor if you should continue birth control for longer than 30 days after the end of the study. If you are unsure whether the method of birth control you use is acceptable to use while participating in this study, you should ask your study doctor before you begin the study. If you are less than one year post-menopausal, there is the potential that you could become pregnant. If you or your partner becomes pregnant, or may be pregnant, at any time during the trial, it is important that you tell your study doctor immediately. The study will be stopped.

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, even if you are withdrawn from the study. Your written consent will be obtained separately in the case that this happens.

USE OF YOUR DATA AND/OR SPECIMENS:

The private information and/or samples collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

- Following your therapist's direction to finish the acute inpatient rehabilitation program until discharge
- Indicating any uncomfortable issues to your therapist or the study researcher after each training session
- *Using birth control methods as described in the Description of What's Involved section*

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. You will not be reimbursed for your travel or time that may be required for study visits.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be improving your activities of daily living or reducing your pain or systemic inflammation from early intervention of walking training using EAW, although it is not guaranteed. These benefits may not continue after you discharge from the hospital and stop the walking training.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Physical risks: The U.S. Food and Drug Administration (FDA) has listed the following risks for powered exoskeletons: instability; falls and associated injuries; bruising, skin abrasion, pressure sores, soft-tissue injury; diastolic hypertension (lower number when looking at blood pressure values that is equal to or greater than 90 mmHg) and changes in blood pressure and heart rate; adverse tissue reaction caused from repeated skin-to-metal contact; premature battery failure of the device; interference with other electrical equipment/devices; device malfunction resulting in unanticipated operation error (e.g., device stoppage, unintended movement); and user error. Some of these risks are similar to usual care methods of walking training, and some may not occur. However, we expect that the risks will be similar for walking training with the exoskeleton as with the usual methods. Risks such as instability, falls and associated injuries, and changes in blood pressure and heart rate may be present for walking tests performed in an exoskeleton or other walking training device. Of these risks, mild skin abrasions (e.g., redness that goes away in a few minutes) due to contact with the exoskeleton, or instability with balance may occur frequently for some participants. Other risks like moderate or severe abrasions, pressure sores, falls,

fall-related injuries, device malfunctions, and operator or user errors we expect will happen rarely.

- Psychological risks could include anxiety (e.g., when you begin walking training), altered mood when you complete the questionnaires, and depression (e.g., when you end the study).
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.
Instead of being in this research study, your choices may include joining other existing EAW studies in the Center for the Medical Consequences of Spinal Cord Injury at James J. Peters Veterans Affairs Medical Center.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. There are no early withdrawal procedures that will be required of you.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after your withdraw your authorization if you have an adverse event from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include uncontrolled cardiovascular conditions, orthostatic hypotension, pregnancy, tumor progression, and pressure sores on the contact area with the device.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number 212-824-8370 or 212-241-7073 for the study researcher, Chung-Ying Tsai.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

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

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone numbers, important dates (birth, admission, discharge), e-mail addresses, and medical records number.
The researchers will also get information from your medical record in the Mount Sinai Hospital.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School’s Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting

purposes. I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: New York State Department of Health
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. 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.

For how long will Mount Sinai be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

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

Signature of Witness	Printed Name of Witness	Date	Time