Participant Name:	**Date:**
Title of Study: Amplify Gait to Improve Locomotor Engagement in Spinal Cord Injury (AGILE SCI) Trial	
Principal Investigator: Keith Gordon, PhD	

SUMMARY

This research is being conducted to examine if supplementing a treadmill-based walking intervention with additional balance challenges created by a small cable-driven robotic device is effective for improving the walking balance of people who have had an incomplete spinal cord injury (iSCI). Some individuals in this study will receive high-intensity treadmill training performed in a standard setting. Other individuals will receive high-intensity treadmill training that is supplemented by additional balance challenges created by applying small forces to a belt worn around the waist that will make it more difficult to walk straight. Changes in walking will be assessed using standard clinical measures of strength, sensation and walking function, laboratory-specific measures of walking function, and activity monitors that track the amount of walking done in the home and community. Understanding the effectiveness of this robotic-assisted training will help improve our ability to prescribe appropriate and effective physical therapy.

We are asking you to take part in this research study because you meet the following requirements:

- You are over 18 years of age.
- You have a motor incomplete spinal cord injury.
- Your spinal cord injury occurred more than 6 months ago.
- You are able to walk 10 meters without physical assistance.

If you agree to join the study, you will be asked to complete the following research procedures:

- You will participate in clinical assessment sessions to evaluate your walking function, balance, mobility, and general health.
- You will participate in a 10-week high-intensity gait training intervention.
- You will wear an activity monitor to measure the amount of walking you do in your home and community.

Your participation will include 25 visits to the laboratory over the course of 26 weeks including:

- A total of five clinical assessment sessions each lasting approximately 1.5 hours. These assessment sessions will be staggered to occur before, during, and immediately after the gait training intervention, as well as at a 3-month follow-up session.
- A total of 20 gait training sessions each lasting 1-hour and occurring 2 days per week.
- You will also be asked to wear an activity monitor during three 1-week periods.

All of the clinical assessments and training sessions will occur within the Northwestern University Department of Physical Therapy and Human Movement Sciences (11th floors of 645 N. Michigan Avenue, Chicago, IL).

We cannot promise any benefit to you by taking part in this research. However, all study participants will receive high-intensity gait training under the supervision of an experienced clinician. The benefits of exercise are known to improve physical and emotional well-being. In addition, there is strong evidence that gait training can improve walking speed and endurance. This intervention will also target the enhancement of walking balance, so you may improve aspects of your health and functional walking ability. However, as this is an experimental study, it possible that you may not improve your walking ability by participating. In addition to possible personal improvements, your participation in this research will provide new information that will help us design more effective interventions in the future.

The most common risks of participation are comparable to risks associated with other intense cardiovascular exercise and gait rehabilitation programs. Specifically, the potential risks to participation include:

- Cardiovascular difficulties and fatigue resulting from high intensity walking.
- Musculoskeletal injuries resulting from falls and/or stumbles during treadmill walking.
- Fear of falling that may be brought on by the training environment that is designed to challenge balance.
- Discomfort from the pelvic harness which fits snuggly around the waist and is used to transmit forces to the pelvis from a cable-driven robotic device.
- Emotional or psychological discomfort created by the personal nature of some of the medical history questions, clinical outcome measures, and record of daily stepping activity.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you are interested in participating, a member of the study team will review the full information with you. You are free to not participate or stop participating at any time during or after the consenting process.

INTRODUCTION

You are being invited to participate in a research study that is being carried out at the Edward Hines Jr. VA Hospital. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. The sponsor of the study is the VA Rehabilitation Research & Development Service. If you have any questions about your rights as a human research participant at any time before, during, or after participation, please contact the Institutional Review Board (IRB) at (708) 202-2811 for assistance. If you have questions about this study, you may contact the Principal Investigator, Keith Gordon, PhD at (312) 503-3339.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

Why is this research being done?

Balance deficits are common among people who have had a spinal cord injury. These balance deficits can make it difficult to engage in daily walking activities. However, improving balance through physical therapy can be very challenging. The purpose of this study is to investigate if current methods of retraining walking can be enhanced to more effectively address issues related to walking balance. Specifically, we will examine if changes in walking balance and participation in daily walking activities are different between people with spinal cord injury who engage in high

intensity walking practice on a treadmill with either standard methods or additional challenges created by a robotic device that applies small forces to a person's waist while walking. Knowledge gained from this study will expand our understanding of how people with spinal cord injury learn walking balance and if targeted balance training impacts participation in walking activities.

Who is conducting and sponsoring the study?
The study Principal Investigator is Keith Gordon, PhD. Dr. Gordon holds a joint appointment with the Edward Hines Jr. VA Hospital and Northwestern University. The study is sponsored by the Department of Veterans Affairs, Rehabilitation Research and Development Service.

We are asking you to take part in this research study because you meet the following requirements:

- You are over 18 years of age.
- You have a motor incomplete spinal cord injury.
- Your spinal cord injury occurred more than 6 months ago.
- You are able to walk 10 meters without physical assistance.

Why are current therapies not satisfactory?
A major consequence of spinal cord injury is an impaired ability to walk. Balance deficits are one of the factors that can make it challenging for individuals with spinal cord injury to engage in daily walking activities. Improvements in walking balance following current gait rehabilitation methods are highly inconsistent. Many individuals with spinal cord injury who regain the ability to walk independently still experience deficits in their balance. Thus, the development of more effective rehabilitation methods that are able to improve walking balance could be used to improve quality of life for people living with spinal cord injury.

How many people will participate?
This study will enroll up to 46 individuals with incomplete spinal cord injury.

DURATION OF THE RESEARCH

This research study is expected to take four years to complete. Your individual participation in the project will take 26 weeks. Your involvement in the study will occur primarily during the first 14 weeks of your participation. Your involvement during the final 12 weeks of the study will include a single assessment occurring three months after you have completed the training intervention.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen:
You will be asked to make 25 visits to the Human Agility Laboratory. Each visit will either be to evaluate your walking function, balance, mobility, and general health, or to participate in gait training.

Visit 1. Baseline Screening – 1.5 hours. During this initial visit, you will undergo a screening to ensure you meet the study inclusion / exclusion criteria. We will also ask you if you are currently participating in any other research studies. If you meet all criteria, we will then collect information from you about your background and medical history. We will ask questions about your spinal cord injury, the cause of your

injury, current medications, the use of any assistive devices, and falls. We will also have you perform tests to assess your walking speed and function. We will also fit you with an activity monitor that will measure the number of steps you take each day. We will explain to you how to use the activity monitor and ask you to wear the activity monitor every day for the following week. You will return the activity monitor at your next visit.

Visit 2. Pre-training Assessment – 1.5 hours. We will use several standard clinical outcome measures to assess your muscle strength, walking speed, walking balance, and postural balance. You will also be asked to complete surveys to evaluate your balance confidence, quality of life, and bowel-bladder function. These measures will all be administrated by a trained clinician.

Next, we will perform a more detailed assessment of your walking balance. We will place small reflective markers on your legs and hips. The movement of these reflective markers will be tracked by cameras as you walk on a treadmill. During some of the treadmill walking, we will ask you to walk in the manner you feel most comfortable. At one point, we will project two lines on the treadmill that look like a narrow path. As you walk, we will change the width of the path. We will ask you to do your best to stay within the path while you walk.

Visits 3 – 12. Gait Training Intervention – 1 hour per session. The gait training intervention will occur 2 or 3 times per week. Each training session will last up to 60 minutes. The objective each session is for you to perform as much treadmill walking as possible in 45 minutes. The additional time each session will be used as needed for setup and rest breaks.

All training will be directed by a licensed physical therapist. The physical therapist will gradually increase the intensity of training (e.g. walking speed, walking time, and balance challenges activities) every session. For safety, you will wear a trunk harness attached to a passive overhead safety support. During the training sessions you will wear a heart-rate monitor, to provide continuous feedback to the physical therapist on the intensity of the training, and an activity monitor, to measure number of steps during the session. The physical therapist will frequently interact with you during the sessions to assess your level of effort. Based on your heart rate and verbal responses to the physical therapist, the training protocol will be adjusted to increase or decrease difficulty. Some people participating in the study will also wear a belt around their waist that attaches to cables. The cables will be connected to small motors that will be used to apply small forces to the belt during walking. The forces applied to the belt will make it more difficult to walk straight.

Visit 13. Mid-training Assessment – 1.5 hours. Procedures during this visit will be the same as used during visit #2.

Visits 14-23. Gait Training Intervention – 1 hour per session. The gait training intervention will be the same as described for visits 3-12.

Visit 24. Post-training Assessment – 1.5 hours. Procedures during this visit will be the same as used during visit #2. At the conclusion of this assessment, we will fit you with an activity monitor that will measure the number of steps you take each day. We will ask you to wear the activity monitor every day for the following week.

Visit 25. 3-Month Follow-up Assessment – 1.5 to 2 hours. Procedures during this visit will be the same as used during visit #2. You will also be interviewed and asked open ended questions to understand your perceptions regarding effects of our training intervention on your balance confidence, walking activities and everyday life. The interview will take about 15 to 30 minutes. At the conclusion of this assessment, we will fit you with an activity monitor that will measure the number of steps you take each day. We will ask you to wear the activity monitor every day for the following week.

Who will oversee the study procedures?
All assessments and gait training sessions will be overseen directly by a certified physical therapist. This physical therapist is part of the research team. This physical therapist will not be your personal health care provider. The physical therapist will monitor your health and safety during all study activities and will document your specific intervention protocol. If you are injured during any study procedure, the physical therapist will lead any emergency response and will determine if you are able to continue with the study. The physical therapist will also alert you should any changes in the intervention arise.

How will the type of gait training I receive be determined?
Some individuals in this study will receive high-intensity treadmill training performed in a standard setting. Other individuals will receive high-intensity treadmill training that is supplemented by additional balance challenges created by applying small forces to a belt worn around the waist that will make it more difficult to walk straight. We will use a randomization process to determine which type of gait training you receive. The study uses a procedure like flipping a coin, so that you will have a 1 in 2 chance of receiving gait training performed in a standard setting instead of gait training supplemented by additional balance challenges.

Who are the people I will interact with during the study?
You will interact with several members of the research study team. These individuals include: physical therapists who will administer different clinical tests and oversee the training intervention, the principle investigator who oversees the organization of the study and will be present at many assessment and training sessions, and research engineers and assistants who will run the motion capture equipment used to assess your walking during assessments, control the treadmill speeds, and help get you set up for each training session.

Where will the study be performed?
All assessments and gait training will occur in the:

Human Agility Laboratory
Department of Physical Therapy and Human Movement Sciences
Northwestern University
645 N. Michigan Ave, Suite 1114

Do I have to answer all surveys or questionnaires?
You will be asked several questions about your medical history, balance confidence, quality of life, and bowel/bladder function. You are free to skip any questions that you would prefer not to answer.

Responsibility and Expectations of Participants
As a participant in this study, the following will be expected of you:

- Keep your study appointments. If you will miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project or physical therapy without approval from the investigators. Taking part in other research studies or physical therapy without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies.
- Tell the research staff if you sustain an injury either within or outside of the study that might affect your participation.

Photographs, audio and video recordings

During your participation in the study, you will be photographed and videos will be recorded. These images will be collected during both assessment sessions and during select gait training sessions. These photographs and videos help us to monitor your progress. Interview performed after 3 months following training will be audio recorded and transcribed by our researchers. Photographs and video that do not show your face may be used for educational purposes (lectures and presentations) and as part of research presentations and research articles.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks may also occur.

Risks	Due to	Probability
Falling	Walking and balance activities	Low
Fatigue (feeling tired)	Walking and balance activities	Moderate
Injury to joins, muscles, or bones	Walking and balance activities	Low
Emotional distress (fear of falling)	Walking and balance activities	Low

The research team will take steps to minimize the chance of these events occurring. You will wear a safety belt and have an individual walking alongside you in a guarding position to provide you with support and/or physical assistance in the event you stumble or have a loss of balance when walking during over-ground activities. During sessions on the treadmill, you will wear a safety harness to provide support in the case of a stumble or fall. You will be given regular scheduled rest periods throughout the session. However, you may request additional rest time at any point during the session. If during the session you feel that the exercise is too strenuous, please let the staff know so that we can reduce the intensity and/or the duration of the exercise. All activities will be supervised by a licensed physical therapist.

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 if you experience significant harmful effects that do not go away quickly, such as lightheadedness/dizziness, fatigue, or musculoskeletal injury.

The robotic device being used to challenge balance in this study is experimental. Because this is a new device, we do not know all of its potential negative effects, and it cannot be guaranteed that you will be able to continue using this device after the study is over.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care. Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible.

POTENTIAL BENEFITS

We cannot promise that you will get any benefits from taking part in this research study. However, all study participants will receive high-intensity gait training under the supervision of an experienced clinician. The benefits of exercise are known to improve physical and emotional well-being. In addition, there is strong evidence that gait training can improve walking speed, and endurance. This intervention will also target the enhancement of walking, so participants may improve aspects of their health and functional walking ability. However, as this is an experimental study, it possible that participants may not improve walking ability by participating. In addition to possible personal improvements, your participation in this research will provide new information that will help us design more effective interventions in the future.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Hard copies of data will be kept in a locked file cabinet in a locked office space accessible only to the research team.
- Electronic copies of data will be kept on a password-protected and encrypted server accessible only to the research team.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential. If you are a Non-Veteran, you will be given a VA Notice of Privacy Practices (NOPP), and we will ask you to sign an acknowledgement saying that you have received this notice.

Information collected as part of this research could be used for future research studies. Any information that is used as a part of a future study will have all identifiable private information and identifiers removed.

There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory

agencies such as the Food and Drug Administration (FDA), the Government Accounting Agency (GAO), or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of Hines/FHCC, Northwestern University approved study personnel, Northwestern University Accounting Services, and the Northwestern University Compliance unit within the Northwestern University Institutional Review Board. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran and non-veteran research participants. By signing this document, you consent to such inspection.

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

This informed consent form does not give the study personnel permission to access, record, and use your private health information. You will be given a separate HIPAA form which provides more information about how your private health information will be used in this study, who will have access to your records, and how you can revoke (take back) your permission in the future. You will not be able to participate in this study if you do not sign the separate HIPAA authorization form.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:*
You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Participants will be responsible for providing their own transportation to and from the testing facility. If you take time away from work to participate in this research, you will not be reimbursed for costs associated with missing work.

Payment Offered for Participation:
If you agree to take part in this research study, we will pay you $25 for each assessment visit (5 total assessment visits) and $20 for each training session (20 total training sessions) in cash for your time and effort. You will be paid weekly. The funds will be distributed through the Accounting Services at Northwestern University. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

If you require parking, the study team will provide you with a parking voucher for the parking garage at 222 E. Huron St., Chicago, IL at the conclusion of each visit.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility.

This does not apply to treatment for injuries that result from non-compliance by you with study procedures.

If you should have a medical concern or get hurt or injured as a result of taking part in this study, call the study PI:

Keith Gordon, PhD at (312) 503-3339.

Emergency and ongoing medical treatment will be provided as needed. The Department of Veterans Affairs does not normally provide any other form of compensation for injury.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you do not take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctors or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to leave the study early, the investigator may continue to review data that has already been collected for the study but will not collect any further information from you.

SIGNIFICANT NEW FINDINGS

Sometimes during the course of a research study, new information becomes available about the intervention that is being studied that might change a person's decision to stay in the study. If this happens, the study PI will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your study PI could also decide it to be in your best interest to withdraw you from the study. If so, he or she will explain the reasons for this decision.

It is possible a commercial product will be developed as part of this research. Study participants will not share in any profit from products or tests that might be developed based on the results of this research.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

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 if you experience significant harmful effects that do not go away quickly, such as lightheadedness/dizziness, fatigue, or musculoskeletal injury. Participants may also be removed from the research study for missing scheduled study appointment visits without a valid excuse or fail to notifying study team members of their absence. We will provide participants with a warning prior to withdrawal. Participants could also be removed from the study if we learn that they were willfully dishonest when answering our screening (inclusion/exclusion) questionnaire.

Finally, participants could be removed from the study if they arrive for study procedures while under the influence of illegal drugs or alcohol.

CLINICALLY RELEVANT RESEARCH RESULTS

Clinically relevant research results will not be formally shared with participants. However, if participants are interested in knowing the results of any of their outcome measures or assessments, we will verbally discuss the results with them at the end of their training.

RE-CONTACT FOR FUTURE RESEARCH

The following is optional, meaning that you do not have to agree to being contacted about future research opportunities in order to participate in the current research study. Please indicate your willingness to be contacted about future research opportunities conducted by the Principal Investigator of this study.

Yes_____ Please contact me in the future to see if I am interested in participating in other research studies.
No_____ Please do not contact me about participating in future research studies.

ADDITIONAL CONTACT INFORMATION

If at any time before, during, or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint, or offer your input with a person who is not part of the study team, you can contact the IRB Administrator at 708-202-2811.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

_____ / /
Signature of Participant Date Written by Participant

_____
Participant's SSN (last four digits)