# CARILION CLINIC
# CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

**TITLE:** Effect of High-Intensity Gait Training Using a Treadmill on Locomotion Recovery in Traumatic Brain Injury Patients

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## SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study investigator. A brief summary of the study is provided below.

- Being in this research study is voluntary; it is your choice.
- If you join this study, you can still stop at any time.
- Do not join this study unless all of your questions are answered.
- The goal of this project is to determine the benefits of high-intensity walking training on physical and mental abilities in patients following traumatic brain injuries. High-intensity is defined as therapy treatment that needs patients to be working at a higher physical demand resulting in a higher heart rate (HR).
- Since you had a recent traumatic brain injury and have had your walking and balance mobility affected, you may choose to participate in this study.
- There are 2 study groups in this research. One group will receive the high-intensity walking therapy and some low-intensity physical therapy. The other group will receive just low-intensity physical therapy.
- Your participation is expected to last up to 8 weeks. In the first 4 weeks (or until you are discharged from Carilion's rehab services) you are expected to attend sessions for 3 times a week. Each session may last approximately 60 minutes. One month after you are discharged from Carilion's rehab services, you will be asked to come for 1 more visit to complete some assessments as a follow up.
- Assessment tests will be administered on Day 1, at 2 weeks, and at the end of 4 weeks (or on day of discharge) before the therapy session. An additional assessment session will be administered at the end of 1 month after study completion. All these assessments will take approximately 45 minutes.
- There may be no direct benefit from participation in this study. The researchers hope to determine if there is a benefit of high intensity vs low intensity therapy.
- The possible risks to you could be heart conditions resulting in chest pain and shortness of breath, vomiting, abnormal increase or drop in blood pressure or oxygen levels, dizziness, nausea, confusion, tingling or numbness in hands or feet, or pain in any body part.
- Your options other than participating in this study are,



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- receiving standard of care physical therapy outside of this study,
- participating in other similar studies, or,
- not participating in any such studies

- Since these research activities are part of standard of physical therapy care you will be billed for the research activities through your insurance, just like regular treatment.

**The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family and friends.**

## DETAILED RESEARCH CONSENT

**Please read this entire consent form carefully.**

### WHAT IS INFORMED CONSENT?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the informed consent form that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

You are being asked to take part in a research study because you have been admitted for physical therapy to a Carilion out-patient rehabilitation facility due to a traumatic brain injury. The research is sponsored by Carilion Clinic. The person running this study locally is Courtney Perkins, who is a physical therapist in the in-patient rehabilitation unit of Roanoke Carilion Community Hospital. Before you can decide whether to take part in the research, you should be informed about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research subject. Being in this study is voluntary.

Be aware that the role of the study therapist is different from the role of your personal treating therapist. Your treating therapist decides how to treat your specific problem in order to help you. The study therapist treats all subjects under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your therapist questions to help you know more about these different roles.



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## WHY IS THIS RESEARCH BEING DONE?

Previous research has been conducted on the benefits of High Intensity Gait Training (HIGT) in improving walking capacity, balance and mental abilities in stroke patients. High-intensity gait training is defined as therapy treatment that needs patients to be walking at a higher physical demand resulting in a higher heart rate (HR) than what is usually achieved in Low intensity Physical Therapy alone. Although HIGT is being recommended for patients with brain injury, research regarding the benefits of this specifically after brain injury is limited. The purpose of this research is to see if HIGT with low intensity physical therapy improves walking ability, dynamic balance and mental abilities in brain injury patients. Approximately 60 participants will be involved in this study. The duration of participation for each participant will be 8 weeks, or until the participant is discharged from therapy services.

## WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

The project will consist of subjects who have suffered Traumatic Brain Injury (TBI) and who are able to ambulate on a treadmill with or without a harness system.

There are two groups being studied. One group is high-intensity walking physical therapy with some low intensity therapy. The other is low-intensity physical therapy group. It is not clear which treatment group is better. For this reason, the group allocation will be assigned by chance using a method called randomization. Randomization means that the group will be assigned by chance, like the flip of a coin. The chances of being in either group is equal. Although high-intensity walking training is now being recommended by updated practice guidelines for patients with brain injury, very few studies on high-intensity walking training have actually been conducted specifically with people who suffered traumatic brain injury. A recent case study found improvements in walking and balance abilities following high-intensity walking training in a patient with a certain type of brain injury. This study suggested this type of training to be a promising intervention with meaningful functional improvements in brain injury patients.

After signing the consent form and prior to random allocation to one of the two groups, participants will undergo a medical and treadmill screening process at the Carilion out-patient facility to check for safety for participating in the research procedures. The medical screening would be conducted by the physician in our research team. Following medical clearance, the treadmill screening would be conducted by our research team members, with the supervision of a physician. The purpose of this screening is to observe heart rate (HR) and blood pressure (BP) response to walking on a treadmill at gradually increasing speeds or workloads. For this screening, participants would be secured using a harness system to prevent any falls. As participants continue to walk at increasingly higher workloads, HR and BP would be constantly monitored and noted. Treadmill test will end when HR reaches 85% of Heart Rate Reserve (HRR),



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participants drift backwards to end of the treadmill, demonstrate walking instability, or request to stop test. Heart Rate Reserve is defined as the difference between resting heart rate and the maximum heart rate as calculated from participant's age. During this screening, participants would also be instructed to report any signs of chest pain, shortness of breath, nausea, dizziness, confusion, tingling or numbness in hands or feet, body pain, etc., or other discomfort. If they experience any serious events of chest pain, shortness of breath, vomiting, any abnormal changes in blood pressure or oxygen levels, the screening session would be immediately stopped. They would be rapidly evaluated by an onsite medical team member. Appropriate medical care would be provided. A 911 call would also be placed if needed. They would be permanently excluded from any further participation and advised to consult their physician. If they experience any other milder events, like, dizziness, nausea, confusion, tingling and numbness in hands or feet, body pain, they would be constantly asked to determine if they are able to tolerate and continue with the screening. If they are able to tolerate and continue, their symptoms would be documented and they would be cleared for inclusion in this study. If they are not able to tolerate these other symptoms for the duration of the screening and want to stop, the screening would be stopped immediately, they would be excluded from any further participation in this study and would be advised to consult their physician.

Following medical and treadmill clearance, participants would be randomly allocated to either the high-intensity walking physical therapy group or the low-intensity physical therapy group. From this point, participants in both groups would undergo therapy procedures for a period of 4 weeks or until they are discharged from Carilion Clinic therapy services. Both groups will receive physical therapy treatment 3 times per week for 1 hour.

**<u>If you are included in our high-intensity treadmill gait training (HIGT) intervention group</u>**

Your participation is expected to last up to 8 weeks. In the first 4 weeks (or until you are discharged from Carilion's rehab services) you are expected to attend sessions for 3 times a week. Each study visit may last approximately 60 minutes. One month after you are discharged from Carilion's rehab services, you will be asked to come for an additional visit to complete some assessments as a follow up.

For each session, you will undergo 30 minutes of high-intensity treadmill walking. During this period, treadmill settings will be adjusted to keep your exertion levels relatively high. This means that your heart rate level would be maintained in the range of 60-85% Heart Rate Reserve (defined above). During this time, your heart rate and oxygen level will be measured continuously, and your blood pressure will be measured periodically. You will also be asked to notify your exertion levels from time to time. You will be allowed to rest as needed. You will also be asked to notify the researchers if you feel any discomfort, including chest pain, shortness of breath, dizziness, nausea, tingling and numbness in hands or feet, or pain in any body part. If you experience any serious events of chest

pain, shortness of breath, vomiting, any abnormal changes in blood pressure or oxygen levels that might indicate an acute heart condition, your session would be immediately stopped. You will be rapidly evaluated by an onsite medical team member. Appropriate medical care would be provided to you. A 911 call would also be placed immediately. You would be permanently excluded from any further participation and advised to consult your physician. If you experience any of the other milder events, like dizziness, nausea, confusion, tingling or numbness in hands or feet, body pain, you would be constantly asked to determine if you are able to continue the session. If you are able to tolerate and continue, your symptoms would be continuously monitored and documented. If you are not able to tolerate these symptoms and want to stop, your session will be stopped and you will be asked to consult the physician team member for a repeat medical clearance. If cleared by the physician, and if you still want to participate, you may be allowed to continue in the study. The condition for continued participation is not to have any recurrence of these adverse symptoms, limiting your ability to tolerate the entire 30-minute session. If this condition is not met, you will be excluded from further participation in this study. Also, if you are allowed to continue, you will be requested to add any days that you have missed.

After finishing treadmill walking, you will undergo low-intensity physical therapy that could be up to 30 minutes, depending on the time remaining for a total of 1 hour. This would include low-intensity gait activities, exercises (such as lower extremity strength training with or without weights or electrical stimulation, sit to stands from a chair, mat exercises for upper/lower extremities and core strength, etc.), stretches, balance training activities, and other therapeutic activities (such as transfers, bed mobility training, etc.). Just like the high-intensity walking training, here your heart rate and oxygen level will be measured continuously, and your blood pressure will be measured periodically.

You will be assessed using a list of tests that assess walking abilities, balance and mental abilities on the first day of the study, after 2 weeks, at the end of 4 weeks or on your last day before discharge from Carilion's services, and again after 1 month after study completion. These will help assess walking, balance, and improvement of mental abilities during and after therapy sessions. These tests would need about 45 minutes additional time to complete, and so would require extended appointment sessions during those 3 days. The assessment tests will be administered before therapy sessions.

You will undergo all of these research activities at Institute of Orthopedics and Neuroscience (ION) building at 2331 Franklin Rd SW, Roanoke, VA 24014.

**<u>If you are included in our low-intensity physical therapy control group</u>**

Your participation is expected to last up to 8 weeks. In the first 4 weeks (or until you are discharged from Carilion's rehab services) you are expected to attend sessions for


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3 times a week. Each study visit may last approximately 60 minutes. One month after you are discharged from Carilion's rehab services, you will be asked to come for an additional visit to complete some assessments as a follow up. This would include low-intensity gait activities, exercises (such as lower extremity strength training with or without weights or electrical stimulation, sit to stands from a chair, mat exercises for upper/lower extremities and core strength, etc.), stretches, balance training activities, and other therapeutic activities (such as transfers, bed mobility training, etc.). During these sessions, your heart rate and oxygen level will be measured continuously, and your blood pressure will be measured periodically.

You will be assessed using a list of tests that assess walking abilities, balance and mental abilities on the first day of the study, after 2 weeks, at the end of 4 weeks or on your last day before discharge from Carilion's services, and again after 1 month after study completion. These will help assess walking, balance, and improvement of mental abilities during and after therapy sessions. These tests would need about 45 minutes additional time to complete, and so would require extended appointment sessions during those 3 days. The assessment tests will be administered before therapy sessions.

You will undergo all of these research activities at Institute of Orthopedics and Neuroscience (ION) building at 2331 Franklin Rd SW, Roanoke, VA 24014.

## WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible for informing us if you:

1. Have any adverse reactions to any of our research procedures, including chest pain, shortness of breath, dizziness, nausea, tingling or numbness in hands or feet, or pain in any body part.
2. Complete the variety of tests – These tests would need about 45 minutes additional time to complete, and so would require extended appointment sessions during those 3 days.

## WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

Risks would differ based on whether participants are assigned to high-intensity therapy or the low-intensity therapy group. Risks would be higher for the high-intensity intervention group participants.

For participants in the high-intensity group, the possible risks could be heart conditions resulting in chest pain, shortness of breath, vomiting, abnormal increase or drop in blood pressure or oxygen levels, or other milder events like dizziness, nausea, numbness in hands or feet, any pain or soreness in any body part and fatigue.

For participants in the low-intensity group, the possible risks of heart conditions resulting in chest pain, shortness of breath, vomiting, abnormal increase or drop in


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blood pressure or oxygen levels are lower than the high-intensity group. However, the risks of other milder events like dizziness, nausea, confusion, tingling or numbness in hands or feet, or pain in any body part and fatigue are still equally possible.

In addition to these risks, taking part in this research may harm you in unknown ways.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see "What about confidentiality?" section below).

## WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?

There may be no direct benefit from participation in this study. The researchers hope to determine if there is a benefit of high intensity vs low intensity therapy.

## ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?

Your options other than participating in this study are

- receiving standard of care physical therapy outside of this study, which can include therapeutic exercises, balance training activities, stretching exercises, cognitive training and functional training activities including gait training. However, in this type of treatment, your physical therapist generally does not focus on increasing your physical workload by increasing your heart rate. Therefore, this mostly results in low-intensity physical therapy.

- participating in other similar studies, or,

- not participating in any such studies

## WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY OR ABOUT MY STUDY RESULTS?

Sometimes new information comes out during a research study that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about the new information. If you decide you no longer wish to participate, they will also tell you about other options for your care. You may need to sign another form with your consent to continue in the study.

In general, we will keep you informed about how you are handling the research procedures, but we will not discuss the specific results of this study because this is a small pilot study, and results might need to be confirmed using bigger studies. If we find something of urgent medical importance to you, we will inform you at that time.

## WHAT ABOUT CONFIDENTIALITY?

The research records will be kept private on a password-protected computer in a locked office. The master link will be kept on a password protected Carilion secured shared drive computer in a locked office. All research data will be coded with a unique number. Your name and telephone number will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be stored in a locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

We might use your research data in future studies without additional consent from you. These future studies might be done by us or by other investigators. Before we use your data, we will remove any information that shows your identity. There still may be a chance that someone could figure out that the information is about you.

## AUTHORIZATION TO USE YOUR HEALTH INFORMATION:

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

### This is the information about you that researchers will use

- Personal identifiers such as name, telephone number, and medical record number.
- Demographic information such as age, ethnicity, and gender.
- Medical history, including current condition, current or past therapies.
- Tests and procedures that will be done in the study

### The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- The Food and Drug Administration or other government agencies that oversee research with humans.

- Committees that monitor research data and safety or other groups authorized to monitor the study.
- Researchers at the following non-Carilion facilities: Radford University, Virginia Tech

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you end your permission.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

## WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Since these research activities are part of standard of care physical therapy, you or your insurance will be billed for standard medical care and you will be responsible for any medical costs your insurance does not cover.

## WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

You will not be paid for taking part in this research.

## WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you will be able to get treatment. If any adverse reactions or injury occur, nursing and physicians who would be present in your facility during the research activities, would be notified immediately. These nurses and physicians will be familiar with your medical history and treatment plan.

The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation, nor payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

## WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion.

## CAN I BE REMOVED FROM THIS RESEARCH WITHOUT MY APPROVAL?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You become pregnant
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointments

The reason for any exclusion will be explained to you.

## ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

This research study does not have any sponsors or funding at this time. None of the investigators or research staff will receive money or other types of payment for the purposes of being involved in this study.

## WHO ARE THE CONTACT PERSONS?

If you encounter complications or have any questions about the study, you may call:

Courtney Perkins, Carilion Roanoke Community Hospital, Phone number: 440-787-5992
Email: cperkins@carilionclinic.org

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (540) 224-5878 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

## IRB SURVEY:

The IRB committee is a group of people that reviews research to protect the rights of research subjects. One job of the IRB is to make sure the research is done in a way that is respectful to subjects. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research.
_____No, I do not want Carilion IRB to send me such a survey.

ClinicalTrials.gov

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.

**CONSENT SIGNATURES:**

- **Research Participant Box** must be completed .
- **Person Obtaining Consent Box** must always be completed.
- **Witness Signature Box** is optional unless required by the sponsor.
- **Participants must receive a signed copy of this consent form.**

**RESEARCH PARTICIPANT:** The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time.

_____
Printed Name of Research Participant (18 years or older)

_____ _____
Participant's Signature Date

**RESEARCH TEAM MEMBER OBTAINING CONSENT:** I certify I was present for the informed consent discussion. The participant had an opportunity to ask questions about and appeared to understand the information presented. The participant agreed to take part voluntarily in the research and I obtained his/her signature.

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Research Team Member Obtaining Consent Date



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**WITNESS TO SIGNATURE (If required by sponsor or protocol):** As an impartial third party, I witnessed the authorization process and the participant's signature on this form. I confirm that this entire form was read to the participant named above. The participant voluntarily agreed to be in this study.

_____
Printed Name of Witness

_____ _____
Witness' Signature Date

*WHEN THE PARTICIPANT IS PHYSICALLY UNABLE TO SIGN OR MAKE A MARK:*
***I certify the participant gave verbal consent to take part in this research study and gave me permission to sign on his or her behalf.***

_____
***Printed Name of Person Signing for Participant***
***(This person cannot be part of the study team)***

_____ _____
***Signature of Person Signing for Participant*** ***Date***

**TO BE COMPLETED BY WITNESS WHEN PARTICIPANT CANNOT READ:**
I was present during the consent process. The material in the consent form was explained to the research participant. Consent was given voluntarily.

_____
Printed Name of Research Participant

_____
Printed Name of Witness to Consent Process
(This person cannot be part of the study team)

_____ _____
Signature of Witness to Consent Process Date



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