Document Coversheet

Study Title: Rehabilitation Strategies to Improve Outcomes For Patients With a Lower Extremity Fracture

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KEY INFORMATION FOR REHABILITATION STRATEGIES TO IMPROVE OUTCOMES FOR PATIENTS WITH A LOWER EXTREMITY FRACTURE

We are asking you to choose whether or not to volunteer for a research study to determine how two different physical therapy interventions effect recovery of patients who sustain a femur or tibia fracture. We are asking you because you have suffered a fracture to your lower leg. This page is to give you key information to help you decide whether or not to participate. We have included detailed information after this page. Please ask the research team questions you have may have. If you have any questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to determine how two different physical therapy programs influence your function, perceptions of recovery and wellbeing. By participating in this study you will be randomly assigned to receive either standard of care physical therapy or standard of care physical therapy plus an additional treatment.

By doing this study, we hope to learn how to better treat individuals with a lower extremity fracture. Your participation in this research will last about twelve months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will receive complementary physical therapy visits that will be covered by this study. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You should not participate in this study if you are younger than eighteen (18) years of age and older than fifty (50) years of age. Additionally, you should not participate if you are unable to attend physical therapy visits, or are not going to be able to attend follow up visits.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Brian Noehren, PT, PhD of the University of Kentucky, Department of Physical Therapy at 859-218-0581.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You should not participate in this study if you are not between the ages of 18 -50 years, or do not speak English. If you have history of the following, you should not participate in this study:

- History of chronic pain lasting more than 3 months and bothersome at least half the days over the past 6 months that started before the fracture
- Moderate or severe traumatic brain injury
- Initial treatment requiring amputation
- Currently employed for less than 20 hours a week at the time of injury
- Spinal cord injury
- History of schizophrenia, dementia, or neurologic disorder with peripheral dysfunction
- Not able to walk or limited ability to walk without an assistive device prior to the fracture
- Multiple trauma that prevents weight bearing
- Currently pregnant
- Unable to participate in or complete in-person follow-up visits and therapy sessions
- Attending physical therapy outside of the study at the start of the intervention
- Use of an assistive device to walk for community ambulation at the time of enrollment

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the University of Kentucky Turfland Physical Therapy clinic and the University of Kentucky BioMotion Laboratory. Physical therapy visits will happen at the Turfland Physical Therapy clinic. Treatment visits may happen either the Turfland Physical Therapy clinic or the BioMotion Laboratory in the Multidisciplinary Sciences Building at 725 Rose Street, Lexington, KY 40536-0082, whichever is more convenient for you. The research procedure will start 6 weeks after discharge from the hospital. We will start by conducting an initial assessment of how you are walking and have you fill out several questionnaires. We will repeat this after you complete the physical therapy intervention at 6 months. You will be asked to complete questionnaires again at a 12-month follow-up assessment. The total amount of time you will be asked to volunteer for the study visits outside of physical therapy appointments is approximately ten (10) hours.

WHAT WILL YOU BE ASKED TO DO?

If you agree to participate in the study, you will randomly be assigned to 1 of 2 groups. This means that you and your doctor will not choose your physical therapy treatment, but that the treatment will be randomly selected for you (like a coin toss). The two study treatments involve standard of care physical therapy and one has the additional speed walking intervention. As will be described later, you will be closely monitored during all study treatments to make sure you are as safe as possible.

Before your first physical therapy visit, we will have you fill out several questionnaires, taking approximately 15 minutes to complete. Each of these questionnaires contains questions about your lower extremity injury and how it is affecting your daily life and activity level. These questionnaires include the Pain Self Efficacy Questionnaire (PSEQ); and the Tampa Scale of Kinesiophobia (TSK). We will also have you complete the Work Productivity and Activity Impairment questionnaire (WPAI), PROMIS Physical Function, and Brief Pain Inventory (BPI). Additionally, you will complete a demographic questionnaire so we can learn the history of your pain including its location, frequency, and duration. Lastly, we will ask several questions about your work and physical activity history and current status. We will then have you complete these same surveys at the study follow up visits (upon completion of intervention, 6 months, and 12 months after hospital discharge). At the completion of the intervention, we will also ask you to complete a client satisfaction questionnaire (CSQ).

The following functional tests will be conducted before your first physical therapy visit, upon completion of the intervention and at the 6-month follow-up visit:

1. We will also use instrumented insoles (novel gmbh, Germany) to place in your shoes during a 6 minute walk test. These are thin instrumented insoles that measure normal forces when standing and during dynamic activity.
2. Single leg step down test: You will be asked to perform single leg step downs for one minute. You will stand on a box no greater than 10 inches tall and tap your opposite foot to the ground as many times as possible in one minute. This will be repeated once on each leg.
3. Fastest and usual gait speed: We will record your walking speed by having you complete 4 trials of walking along a 20-meter walkway. Two of the trials will be at your fastest speed and the remaining 2 trials will be at your usual comfortable walking speed.

Each study visit should not take more than an hour to complete.

The following Flowchart provides a concise outline of the Study Activities:

Table 1. Flowchart of Study Activities

Visit	Baseline	Upon completion of intervention	6 months	12 months
Questionnaire	X	X	X	X
Step down test	X	X	X	
Walking speed	X	X	X	
Six minute walk test	X	X	X	

Physical Therapy Sessions: We are comparing two physical therapy interventions; one is the standard of care and the other is the standard of care plus an additional treatment. You have a 50/50 chance of receiving either treatment. You will start the physical therapy treatments after you have completed your pre-intervention assessment. One treatment program will focus on assisting you walk as fast as you are comfortable for several intervals. While walking, we will monitor your heart rate with a heart rate monitor and ask you to rate your exertion and pain. The other program will perform exercises to strength your legs. Your physical therapy sessions (12 visits over 4-6 weeks) are covered by the study and will occur at the University of Kentucky physical therapy clinic Turfland location. The physical therapists administering the treatments work closely with the research staff and are well versed in these forms of rehabilitation. The physical therapist will reassess your range of motion at baseline, after every third session, and at the end of the intervention and document the changes. The physical therapist will also record your pain levels, exertion, and heart rates. You will also be issued a home exercise program and asked to track how frequently you complete it.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risks of the fast walking program are that you may feel unsteady or fall. You will be closely watched by the research team during testing to minimize the risk of fall and we will use a safety harness. Also, with exercise you may feel some discomfort in your thighs due to muscle soreness.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect. Lastly, while all attempts are made to maintain confidentiality there is the risk that it may be breached.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

Your physical therapy visits during the study will be covered. You will also receive several detailed evaluations of your functional abilities as you recover.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, you may choose standard of care as directed by your physician.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs to you for participation in this study. The costs of attending the physical therapy visits will be covered by the sponsor (The Department of Defense). There are no-copays that you will have to pay for the 12 visits of the physical therapy covered during this study. The cost saving for not having to pay the copay will be dependent on your specific insurance plan.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

Therefore, the costs of the physical therapy, and functional tests being done strictly for research will be paid by the University of Kentucky.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. You will be assigned an identification number to protect your confidentiality. Hard copies of data will be stored in a locked filing cabinet. Electronic data will be stored on a password protected computer. Access to your information will be limited to the Principal Investigator and other team members. Collected data will be aggregated and presented without identifying information for individual subjects. Hard copies of the data and video tapes will be stored for six years following conclusion of the study at which time they will be shredded and disposed of properly.

Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

You should know, however, that there are some circumstances in which we may have to show your information to others. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

Officials of the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Brian Noehren at 859-218-0581 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly. Therefore, these costs are your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive $20 for each physical therapy visit attended, up to $240. You will receive $100 for each follow up study visit (post-treatment, 6 months, 12 months) for a total of $300. In addition, we will validate your cost of parking. You will also receive a free T-shirt for participating in this study.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 4 times per year.

Do you give your permission to be contacted in the future by Brian Noehren, PT, PhD, regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer for this study, you may be one of about sixty people to do so at the University of Kentucky. The United States Department of Defense is providing financial support and/or material for this study.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

STORING AND SHARING YOUR INFORMATION FOR FUTURE USE:

The researchers would like to store, use, and share your identifiable information for future research. Having information from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information to learn more about rehabilitation of lower extremity fractures or research additional scientific questions.

WHERE WILL INFORMATION BE STORED AND FOR HOW LONG?

The information will be stored in a locked cabinet at Wethington 419 or B04 in the Multidisciplinary sciences building for no longer than six years, after the conclusion of the study.

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?

There is a risk that someone could get access to the stored information. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

HOW WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

Researchers will take careful steps to keep your information confidential.

Researchers will remove your name or other direct identifiers from your information. We will label your information with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you.

HOW WILL WE SHARE YOUR INFORMATION WITH OTHER RESEARCHERS?

Your de-identified information may be shared with other researchers without your additional informed consent, provided an Institutional Review Board (IRB) has approved this action. An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests your information with identifiable information, an IRB will decide if the research may be conducted with or without your additional consent.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION?

You may withdraw your permission to allow your information to be used for future research. To do so, you must send a written withdraw request to:

Brian Noehren PT, Ph.D.
Professor
University of Kentucky Division of Physical Therapy
Wethington Bldg Room 204J
900 S. Limestone
Lexington, KY 40536-0200

Any remaining information will be destroyed. In addition, it may be possible to destroy the code that links you with your information. However, the information that have already been used or shared may not be withdrawn.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The information that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information.

OPTIONAL FUTURE USE:

Do you give permission for your identifiable information to be stored, used, and shared for future research?

☐ Yes ☐ No Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored or shared for future research.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

Demographic information, medical history for inclusion/exclusion purposes, surgical procedures performed, physical therapy notes for compliance with rehabilitation, radiographic data, and blood test results. **The Researchers may use and share your health information with:**

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- Department of Defense;

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Brian Noehren PT, Ph.D. inform him of your decision.

Brian Noehren PT, Ph.D.
Professor
University of Kentucky
Division of Physical Therapy
Wethington Building Room 204J
900 S. Limestone
Lexington, KY 40536--0200

- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ _____
Signature of research subject **Date**

_____
Printed name of research subject

_____ _____
Printed name of [authorized] person obtaining informed consent and HIPAA authorization Date