Reducing Fall Risk with the use of Neuromuscular Electrical Stimulation to Maximize the Hip Abductor Muscles in Older Veterans

NCT04969094

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Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: Reducing Fall Risk with the use of Neuromuscular Electrical Stimulation to Maximize the Hip Abductor Muscles in Older Veterans (MAIN CONSENT)

Principal Investigator: Odessa Addison, PT, DPT, PhD Facility: VA Maryland Health Care System

IRB Study Number: HP-96177
Sponsor: Veterans Health Administration

INTRODUCTION: You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS) and the University of Maryland, Baltimore. 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.

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.

CONCISE SUMMARY

Older adults are more likely to fall than young adults. Balance training has been shown to reduce the risk of falls. Muscle strengthening may also be important for preventing falls. As we age it becomes more difficult to strengthen muscles and the use of neuromuscular electrical stimulation (NMES) may improve the ability to strengthen muscles. NMES makes muscles contract, which can make them stronger. We have developed a balance program (Multimodality Balance Intervention; MMBI) that when combined with NMES may result in improved balance. The purpose of this study is to see if the addition of NMES to muscles, when combined with MMBI is effective at improving balance and muscle strength. We are asking you to participate in this study because you have either fallen in the past year or you feel as though you are at risk of falling. Having successfully met all eligibility criteria as confirmed by our two screening visits, you are now being asked to participate in the main study that includes 12 weeks of an exercise program aimed at decreasing your fall risk. During this study you will be asked to undergo a number of tests including: body composition testing, strength testing, and tests to determine how well you can walk and move. These tests are conducted before and after the 12 weeks of supervised exercise as well as 6 and 12 months after you finish the exercise program. You will also be asked to report any falls you may experience for the 12 months after you complete the exercise program. There are risks to participating in this study including a risk of falls, muscle soreness or fatigue or chest pain or injury during the exercise. You may be paid up to $225 for participation, depending upon how much of the

study you complete. If you are interested in learning more about this study, please continue reading below.

RESEARCH DETAILS

PURPOSE OF THE STUDY

Falls in older adults are a serious problem. People who fall, or who have a fear of falling reduce their activity and this may accelerate the progression of other age-related disorders. Balance training and muscle strengthening are one way of reducing the risk of falls. This study is designed to determine whether the addition of neuromuscular electrical stimulation (NMES) applied to the hip abductor muscles during a balance and strengthening programs helps to reduce fall risk compared to just a balance and strengthening program alone. We invite you to participate in this research study under the direction of Odessa Addison, PT, DPT, PhD. If you decide to participate in this study, you will be one of about 100 patients asked to participate in this study.

STUDY PROCEDURES:

You will undergo 5 phases of study participation after signing this consent form: baseline testing (phase 1); 12-weeks of exercise (phase 2); post-testing (phase 3), 6-month testing after completion of exercise (phase 4), and testing 12-months after completion of testing (phase 5). Your participation in the study is expected to last ~16 months. In order to participate, you must agree to follow your assigned program and attend your testing sessions. All tests and the exercise training procedures will be completed at the Baltimore VA facilities (Baltimore VA Medical Center, Baltimore VA Annex and VA Loch Raven Outpatient Center) with the exception of two study visits to the University of Maryland Baltimore.

Phase 1: Baseline Research Testing (Total of 6-7 hours over 2-4 weeks)

The order of the tests will depend on your schedule and the availability of appointments. Some of the tests can be performed during the same visit. All of these tests will require a total of 4-5 visits during a 2-4 week period. The testing period may take longer than 2-4 weeks if tests need to be repeated or rescheduled.

Balance and Functional Assessments (60-70 minutes): We will measure your balance, fall risk, and walking ability with seven different tests. These tests include a four square step test (seeing how well you can step over canes on the floor), the modified physical performance test (MPPT; a

test of how well you can perform activities such as standing from a chair, and putting on a coat), the Mini-Best Test (a balance test that asks you to perform activities such as walking, standing on one foot, and turning), and the Functional Gait Assessment (another balance test that asks you to perform activities such as stepping over an object and walking backwards), your grip strength (you will be asked to squeeze a machine that measures the strength of your hands) and how fast you can ascend and descend a flight of stairs up to four times. Your endurance will also be tested while you walk on an indoor course to see how far you can go in 6 minutes.

Strength Test (60 minutes): After a brief warm-up we will measure the strength of your leg and hip muscles by asking you to bend or straighten your knees against a machine as hard as you can. You will also be asked to repeat this test on your hip muscles. You may be asked to lay on your side while we are testing your hip muscles and move your legs up and down so we can measure the strength of your hip muscles. We may slowly increase the resistance until you move the most weight you can. We will give you rest breaks as needed. This test will be stopped if you become uncomfortable.

Body Composition (3 hours): You will lie comfortably on a large machine (DXA) while your body is scanned to measure body fat and muscle mass. You will also undergo CT scans of the abdomen and legs that will also tell us about your body fat and muscle mass. Both the DXA and CT scans are painless, but do involve exposure to low doses of x-rays. Each of these scans will take less than 45 minutes to complete. You will be asked to attend one additional session at the University of Maryland Baltimore, Allied Health Research Building. There you will undergo an ultrasound of your legs that will give us more information about your muscle mass.

You may also be asked to undergo a single Magnetic Resonance Imaging (MRI) scan of your hips and legs however not every participant will be asked to do this. If you are asked to do this, it will be one additional session. This will give us more information on your muscles and the tendons that connect your muscles to bones. If you are asked to undergo this scan you will lay comfortably on your back. This scan is painless, and does not exposure you to any additional radiation. It will take approximately 30 minutes to complete. You will be asked questions in private by a study team member to determine if you can undergo an MRI scan and to evaluate your situation. The MRI scanner has a very strong magnet inside, and no metal can go near it. If you have metal in your clothing, you must change into MRI safe clothing before the scan. After you are cleared to undergo MRI, you will go into the scanner room. A technologist will place you on a table. This table will move you inside the MR scanner. The scanner has cameras and a microphone, which will always monitor you and ensure your safety. You can talk to the technologist through the microphone while

you are in the MRI. The MRI scan takes several pictures. Some pictures take longer than others. The technologist will tell you how long each picture will take. Remember, you can always stop the scan if you are uncomfortable. After the scan is complete, the technologist will take you out of the scanner. You are then free to change back into your clothing and leave the premises.

Questionnaires (30 minutes): You will be asked to complete three questionnaires about your balance (the ABC scale), quality of life (Late in Life Disability Instrument), and how well you are able to complete daily activities (Late In Life Disability Function).

Walking Assessment (90 minutes): We will ask you to walk a short distance and we may place sensors on your legs to record your movements. The sensors on your legs are small and worn while walking to tell us about how consistent your movement are while you walk. Additionally, your movements will be recorded by motion-detecting cameras that will record the movements of the small reflective markers we place on your body and legs. Surface electromyography (EMG) sensors may also be placed on your skin over your muscles to collect information about how your muscles are activated while you walk.

Physical Activity Assessment (1 week): You will be asked to wear an activity monitor on your wrist, waist, or ankle for up to one week while going about your normal activity.

A summary of all study procedures can be found below in the Study Testing Table

Participant Name: _____ Date:_____

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Principal Investigator: Odessa Addison, PT, DPT, PhD Facility: VA Maryland Health Care System

Study Testing Table

Testing Category	Required Tests
Balance and Functional Assessments (60-70 minutes)	
	Four-Square Step Test Modified Physical Performance Test Mini Best Test Functional Gait Assessment Grip Strength Stair Climb Test Six-minute Walk Test
Strength Tests (60 minutes)	
	Knee Strength Hip Strength
Body Composition (3 Hours)	
	DXA CT scan Ultrasound (This will be done at University of Maryland Baltimore) MRI
Questionnaires (30 min)	
	ABC Scale Late in Life Functional Disability Instrument Late in Life Disability Function
Walking Assessment (90 minutes)	
	Walking with sensors Motion Detecting Cameras Surface electromyography
Physical Activity Assessment (1 week)	
	Wearing physical activity monitor (This will be done at home)

Phase 2: 12 weeks of fall prevention exercise
After Phase 1, you will participate in the MMBI classes (details below), regardless of group assignment. Additionally, you will be randomized (similar to flipping a coin) to either receive or not receive NMES during the strength training.

MMBI classes: For 12 weeks you will exercise in the MMBI group. You will attend exercise classes, 3 times per week for an hour. A skilled instructor will lead each class with 1-2 assistants present to assist with fall risk prevention. The classes will consist of a group balance class (30 minutes), a supervised obstacle course (10 minutes), and lower body and core body strength training (20 minutes). You will start exercise at a very low level. Over the 12 weeks of the class, the exercises will gradually increase in difficulty to challenge your balance.

NMES: If you are randomized to the NMES group, during the lower body and core strengthening exercises of MMBI you will be asked to wear a NMES unit. Two small pads will be placed on each of your hip muscles. You may also be taught how to place these pads by a skilled assistant. The unit will be turned on until you feel a strong but comfortable sensation in your hip muscles that cause the muscles to contract. You will start out at a very low level and over 12 weeks of exercise will gradually increase in intensity.

Phase 3: Post-Testing (Total of 5-6 hours over 2-4 weeks)
12-weeks after beginning the intervention you will have repeat testing (same as Phase 1 testing see study testing table for summary). You will be asked to continue with your assigned exercise group activities during this phase until all testing is complete. You will also be given a home exercise program to participate in for the rest of the study.

Phase 4: 6-months post-exercise testing (total of 5-6 hours over 2-4 weeks)
Six-months after the completion of the exercise intervention you will have repeat testing with the exception of the ultrasound test (same as Phase 1 testing see study testing table for summary). You will also be asked to either use the Annie App to respond to weekly questions about if you have had a fall or loss of balance. The Annie App is a VA supported phone app that will ask you if you have had a fall or loss of balance. You can respond via text message and your answers will be securely recorded for our study staff. If you choose not to use the Annie App, you may also return monthly post-cards to us to document any falls you have had during that time. We will also reach out to you monthly to see if you have any questions about your home exercise program during this time.

Phase 5: Final Research testing (total of 5-6 hours over 2-4 weeks)

12-months after the exercise intervention will have repeat testing with the exception of the ultrasound test (same as Phase 1 testing see study testing table for summary).

You will not be enrolled in this study unless you agree and are willing to follow study procedures. You may be asked to repeat one or more of the tests within a given phase if there is an error in its measurement, if a sample is too small for measurement, or there was an unexpected problem with data collection. You will be told about findings of tests that have a direct effect on your health.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

New findings may develop during the course of the research that may affect your willingness to continue participation. If this occurs, these findings will be provided to you. If abnormalities are detected from the body compositions tests, we will tell you and with your permission, the results will be forwarded to your private doctor.

FUTURE USE OF DATA AND RE-CONTACT

In the future, researchers may need more information about you, or may ask you if you are willing to participate in a new study. Please initial below your preference for being re-contacted. You may change your mind about providing information in the future by informing Dr. Addison at 410-605-7000 ext. 55393.

I can___ cannot____ be re-contacted for information.

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

If you take part in this research, you will be responsible to come to your research testing and training visits at the VAMHCS, follow the instructions of the research team, and notify staff in advance if you need to cancel or reschedule appointments.

POTENTIAL RISKS/DISCOMFORTS:

1) Balance and Functional Assessments: There is a small risk you will fall, experience chest pain, or become short of breath or dizzy during these tests. The person doing the test will stop if you have any symptoms such as chest pain. We have performed >1000 functional tests without complications. We have taken care to reduce risks and the exercise technician doing these tests is trained in CPR.

2) Strength Test: There is a small risk that your leg or hip muscles may become tired or strained during this test. You will be given regular rest breaks between repetitions to reduce your tiredness. A small risk of skin irritation or bruising is also possible from the testing machine. This usually goes away within a few days. We will reduce this risk by applying padding and checking your skin before and after tests.
3) Body composition: The radiation dose which you will receive as a result of taking part in this study includes radiation from DXA and CT scans. Using the standard way of describing radiation dose, you will receive 351 mrem to your total body in one year. Please be aware that this radiation exposure is necessary for research purposes only and is not essential for your medical care. The University of Maryland Baltimore (UMB)/ VA Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being within the UMB/VA Radiation Safety Guidelines for research subjects of 3000 mrem to any tissue In a 13-week period and 5000 mrem in one year. The radiation dose you will receive to your whole body is in the range of 300-5000 mrem, which is equivalent to the exposure limit of 5000 mrem per year that is established for radiation workers such as physicians and X-ray technologists who work with radiation and this level of exposure has never been associated with any definite adverse effects. Please advise your doctor if you have taken part in research studies at UMB or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine studies, e.g. thallium scan of your heart, and scans of your brain. Ultrasound is a safe test with no known side effects.

   The MRI scan: MRI has no ionizing radiation and is safe when used on participants who are appropriately screened for safety contraindications. Some medical conditions may prevent you from having an MRI scan. If you do not have any of these medical conditions, you are at no risk during MRI. The MRI scanner has a very strong magnet inside, and no metal can go near it. Moving in the MRI scanner ruins the pictures. Please remain as still as you can during the scan. This may cause temporary muscle stiffness or soreness. Please, let the technologist know if you are uncomfortable. The MRI scanner makes a loud knocking sound. The knocking sound depends on the type of scan. You will be given ear protection for the scan. If the sound is still too loud, notify the staff. It is possible that you may experience claustrophobia or become anxious when you are inside the scanner. If your

distress is severe, notify the staff. Remember, you can always stop or refuse the scan if you are uncomfortable.

4) Questionnaires: There is no physical risk to completing our questionnaires. However, you potentially might experience psychological stress filling out these questionnaires.
5) Walking Assessment: There is a small chance your muscle or joints become sore or fatigued from walking and standing. There is also a small risk of falling. This test will be done by people trained in safety precautions to minimize this risk and you will be given adequate rest breaks to minimize this risk. Skin irritation is also possible from placing the reflective markers, or the surface electromyography (EMG) sensors. If this occurs, it generally goes away within a few days.
6) Physical Activity Assessment: Skin irritation is possible from wearing the physical activity monitor. If this occurs, you will be able to move the monitor to another location. If skin irritation occurs, it generally goes away within a few days.
7) MMBI training: Due to the nature of the training required to improve balance, there is a risk of stumbling or falling during the balance training portion of the exercise session. To minimize fall risk, trained exercise physiologists and medical personnel are stationed appropriately to assist you during the balance training. During the strength training, there is a risk of tenderness or swelling around the joints or muscles. You may also experience some muscle soreness. The risk of more serious injury such as a sprain is small. This is minimized by having trained exercise specialists to teach you the proper way to do the exercise, and also to watch over you while you exercise. The exercise technician will stop you if you have any significant symptoms such as chest pain, dizziness, arm or leg pain. All exercise training sessions will take place at the Baltimore VAMC Annex or Loch Raven Rehabilitation Gym. They will be supervised by exercise physiologists who are certified in exercise training and CPR. A clinical provider is on call and can be reached by phone for consult in case of any problems. An AED is available on-site and should there be any unanticipated medical emergencies staff can initiate emergency care by calling 911. If 911 is activated, you would be taken to the nearest available hospital for care. We believe that it is highly unlikely that you will develop a medical emergency that would require the 911 system to be activated as in more than 25 years of training more than 1000 research subjects we have only had 1 subject who had a heart attack during aerobic training.
8) Neuromuscular Electrical Stimulation (NMES): The risks associated with NMES include skin irritation and muscle soreness. The risk of skin irritation will be reduced by giving you proper training in the beginning where we can watch and check you to make sure that you

are correctly using the NMES unit. The risk of muscle soreness will also be reduced by gradually increasing the amount of time and strength of stimulation, starting at a low level and slowly increasing as tolerated.

9) Privacy: The risk of providing your health information is that a breach of confidentiality may occur. Results from the body composition testing (CT/DEXA) will be available in your electronic medical record stored at the VA. It is possible that VA medical Center Staff may access this record. This risk will be reduced as your health information will only be used by Dr. Addison, her research team, and VA Medical Center Staff. Additionally, Dr. Addison and her research team undergo training on the Health Insurance Portability and Accountability Act (HIPAA) and the Veterans Health Administration Privacy Policy in order to protect your privacy to the best of their abilities within state and federal law. Loss of confidentiality will be minimized by storing data in a secure location such as locked office and locked cabinet. Electronic data will be stored in secure databases.

In addition to the risk described in this form, there may be unknown risks/discomforts involved in participating in the study. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. The benefits of participating in this study may be: You will receive information about your risk factors for falls. These tests will help you to know you risk of falls compared to others, and whether or not you have an immediate health concern. Your participation in an exercise program may also result in general heart and muscle strength benefits as well as potentially reduce your risk of falls.

ALTERNATIVES TO PARTICIPATION

The following alternative procedures or treatments are available if you choose not to participate in this study: You may choose not to participate in this study without any risk of penalty or loss of benefits to which you are entitled. Your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected. You could pursue exercise or fall reduction programs outside of this program.

COSTS TO PARTICIPANTS

- Transportation to the Baltimore VA Medical Center is the only cost to you. Parking at the medical center, and all research tests are free to research participants.
- You will not be charged for any treatments or procedures that are performed for research purposes in 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.

PAYMENT/REIMBURSEMENT TO PARTICIPANTS

- You will receive the following:
  - $25 after you complete Phase 1 - Baseline testing
  - $100 after you complete Phase 3- Post-exercise testing
  - $25 after you complete Phase 4- 6-months post exercise testing
  - $75 after you complete Phase 5-12-months post exercise testing.

- You will be reimbursed by cash from the Baltimore VAMHCS.
- You will additionally be given a voucher for parking at the University of Maryland Baltimore as needed for your two research visits to that location.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VAMHCS will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

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

Dr. Brock Beamer at 410-605-7000 ext. 54870 during the day, or 301-996-1065 after hours

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the VAMHCS Office of Research Compliance and other representatives of this organization. Study records can be reviewed by federal agencies, can be reviewed by federal agencies, VA Office of Research & Development (ORD) (if VA-funded, VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and the Office of Human Research Protections (OHRP). The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access.

Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

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.
If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

Participant Name: _____ Date:_____

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Principal Investigator: Odessa Addison, PT, DPT, PhD Facility: VA Maryland Health Care System

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, research tests and exercise training records.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the UMB Institutional Review Board, VAMHCS Office of Research Compliance (ORC), Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Office (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Addison and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we cannot ask for your additional consent.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Odessa Addison, PT, DPT, PhD at 410-605-7000 extension 55393.
There are no adverse consequences (physical, social, economic, legal, or psychological) if you decide to withdraw from this research study.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data. You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

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 missing study appointments, failure to follow instructions of the research staff, if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study. If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, or if you have any questions, concerns, complaints, you may contact:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Research Protections Officer (RPO).
VAMHCS Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56510

The VAMHCS Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Participant Name: _____ Date:_____

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Principal Investigator: Odessa Addison, PT, DPT, PhD Facility: VA Maryland Health Care System

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Your signature indicates that the research team member obtaining consent 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.

Furthermore, by signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for 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.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

_____ Person Obtaining Consent (Print)	_____ Consenter's Signature	_____ Date