**SHEPHERD CENTER**
**RESEARCH PATIENT INFORMATION AND CONSENT FORM WITH AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION**

**PROTOCOL#: 738: Comparative Effectiveness of an Exercise Intervention Delivered via Telerehabilitation and Conventional Mode of Delivery**

**Principal investigator: Deborah Backus, PT, PhD**

## Background

New research shows that exercise is good for people with multiple sclerosis (MS) and may decrease symptoms and improve health and mobility. However, people with MS often face barriers to exercise, such as transportation issues, knowing how to exercise safely, and lack of motivation and confidence to overcome barriers. An exercise program that incorporates ways to overcome these barriers may help improve mobility as well as decrease fatigue.

This study will compare the outcomes of a 16-week exercise program conducted at home to a program in a gym. A trained "coach" will teach participants how to exercise and provide encouragement throughout the program. Participants will take assessments before starting the program, two months into the program, at 16 weeks, and at 12 months after starting the program. The study is funded by the Patient-Centered Outcomes Research Institute ("PCORI"). We hope that the findings will make exercise and its benefits more available to people with MS who have mobility difficulties.

## Study Purpose

To assess whether an at-home exercise program produces the same health and wellbeing outcomes as an exercise program based in a gym.

You may participate in this study if you:

1. Have mild to moderate MS
2. Are between 18 and 65 years old
3. Can travel to the Study Site (Shepherd Center) for the required training sessions and assessments
4. Have the required technology (i.e. computer or DVD player and TV, and phone)
5. Score between 4.0 and 6.5 on an assessment called "the Expanded Disability Status Scale"
6. Are medically stable or can obtain medical approval to participate in exercise studies
7. Can walk 25 feet in 6 seconds to 3 minutes
8. Can read, write, and speak English

You may not be enrolled in this study if you:

1. Have had an MS relapse in the past 30 days
2. Have had a fall in the past three months that the study investigator determines makes participation unsafe
3. Already exercise at recommended levels

4. Have other neurological (e.g., stroke) or musculoskeletal conditions or other co-morbidities
5. Have severe cognitive difficulties and cannot follow simple directions
6. Are physically unable to complete two trials of the walked test called "The Timed 25 Foot Walk Test"
7. Have any other concern that the investigators think would jeopardize your safety.

## Duration and Scope

This study involves exercising for about one hour twice per week for 16 weeks, and four test sessions. If you agree to participate in this study, you will be randomly put into one of two groups. People in one group will exercise using a program at home, and another will exercise at the Study Site. Both programs require that you exercise by yourself using the exercise instructions given to you. You will also meet regularly with a coach. If you are in the home exercise program, you will talk with your coach using video conferencing or on the phone. If you are in the program that comes to Study Site, you will meet with your coach in person.

If you agree to participate, you will need to complete further testing, or assessments. One session for testing will take place before you start the program, and the others will happen 2-months into the program, immediately after the 16-week program, , and finally, 12 months later. The assessments mostly involve answering questions about your multiple sclerosis and exercise habits. There will be two assessments that measure how far and how fast you can walk.

## Exercise Program

Except for the 2-month assessment, which you may take on a computer at home, testing will take place at the Study Site. If you are in the home exercise program, called "Telerehab", you will do your exercises at home. Telerehab is short for "telerehabilitation" and means you will receive assistance from a coach via technology instead of in person. If you are placed in the Study Site exercise program, called "Facility-based", you will exercise in a Study Site gym facility.

**Exercise program description: You will be in one of the following groups, and will follow the instructions for that group only.**

Telerehab Program: The University of Alabama developed and will oversee this program. You will exercise two times per week in your home using instructions on a DVD or computer. The exercise program should take about one hour each day. You will have a dedicated coach to get you started, answer your questions, and support you throughout the program. There are three

exercise difficulty levels that you can choose from with the help of your coach. You will have regular meetings with your coach by video conference, such as "Zoom", or by phone. We will give you all the equipment that you need for the exercises. Equipment includes resistance exercise bands and a pedometer that you will wear to track your steps. You will be allowed to keep these when the study ends.

Facility-based Program: This program contains the same exercises, but you will conduct the exercises in one of the Study Site gyms. Equipment includes resistance exercise bands and a pedometer that you will wear to track your steps. You will be allowed to keep these when the study ends. You will meet with your coach in person at regular intervals to coincide with your exercise times.

Whether you are in the Telerehab or Facility-based group, you will keep an exercise log to track how many times you exercise and for how long. The Telerehab group will enter their exercise log information into the study Portal – a secure, HIPAA-compliant, online database. If you have pain, injury, or any additional complaints of being tired, you will write the information in your log and tell your coach immediately. The coach will stop the training and discuss the event with the principal investigator.

**Assessments description**

Visit 1/Assessment 1: Visit 1 may take between 2 and 4 hours to complete. At this visit, you will either agree or decline to participate in the study. If you decline, your visit ends.

If you agree to participate in the study, we will ask you to take the following four tests:

- The "Timed 25 Foot Walk Test." This test times how long it takes you to walk 25 feet. To be eligible to participate in the study, your time must be between six seconds and three minutes. You will conduct this test twice. Only one walk time must be within the eligible timeframe. However, to be eligible to proceed, you must complete the test twice.

- The "Six-Minute Walk Test." For this test, you will walk for six minutes at your own pace. We will measure the distance that you walk.

- A test called the Expanded Disability Status Scale, or "EDSS." This measures your walking ability. If your score is not between 4.0 and 6.5, you will not be able to participate in the study.

- The "Mini Mental Status Exam," which measures your ability to follow simple commands. If your score is greater than or equal to 19, you will be eligible to participate in the study.

Once you are eligible to participate in the study, we will ask you some questions about "health literacy," which is how easy or difficult it is for you to understand and use health information. Next, we will help you create a study Portal account. On the Portal, you will answer some final survey questions about your MS symptoms, how MS impacts your life, demographics, and exercise habits. A researcher will help you if you have any questions. You will be able to take small breaks, if you need them. The surveys will include:

1. Demographics and medical history asks questions about your demographics and MS history
2. Multiple Sclerosis Walking Scale-12 will ask you how MS impacts your ability to walk
3. The Modified Fatigue Impact Scale will ask you questions about fatigue and if it affects your ability to function;
4. The Neuro-Quality of Life assessment will ask you questions about the impact of MS on your life;
5. The Multiple Sclerosis Impact Scale which measures the impact of MS on day-to-day life.
6. The Exercise Self-Efficacy Scale will ask you about your confidence to undertake exercise;
7. The Exercise Goal Setting Scale will ask you questions about your exercise goals;
8. The Multidimensional Outcome Expectancies for Exercise Scale will ask you about your beliefs about the benefits of exercising and any barriers to exercising that you have;
9. The Social Provisions Scale will ask you about if you have personal relationships that support you to exercise;
10. The Physical Activity Self-Regulatory Scale will ask questions to understand how you feel about exercising.
11. Exercise Barriers will ask you questions about barriers you experience when exercising

12. Barriers for self-efficacy will ask you about your self-confidence to exercise when you experience barriers

These assessments provide us with "baseline" measures before you start the exercise program. At future assessments, we will see how these measurements change.

After you have completed all the assessments, the computer will randomly place you into one of two groups. Group 1 is called "choice" and group 2 is called "random." If you are in Group 1, you will choose whether you want to be in the Telerehab or Facility-based exercise program. If you are in Group 2, the computer will randomly place you into either the Telerehab or Facility-based program.

Before you leave, the research personnel will give you printed information to take home. The information will include a copy of this form and a list of the next steps. If you are in the Telerehab program, research staff from the University of Alabama who are overseeing Telerehab, will contact you. If you are in the Facility-based program, a coach from the Study Site will contact you to schedule your first visit.

Assessment 2:

This assessment takes place eight weeks after you start the exercise program. You will not need to visit the Study Site to take this assessment. Instead, you will log into the study Portal and answer many of the same questions as assessment 1, plus the Godin Leisure Time Exercise questionnaire.

Visit 2/Assessment 3:

This assessment takes place immediately after you finish all 16 weeks of the exercise program. You will need to visit the Study Site for this assessment. The tests are the same as the ones you did during Assessment 1. You will repeat the Timed 25 Foot Walk Test, the Six Minute Walk Test, and the Expanded Disability Status Scale and answer the same survey questions on the computer, plus the Godin Leisure Time Exercise questionnaire and a feedback survey.

Visit 3/Assessment 4:

This assessment takes place 12 months after you finish the exercise program and is the same as Assessment 3, minus the feedback survey. You will need to visit the Study Site for this assessment.

## Risks associated with the study

Participating in this study poses a low risk. All participants will take part in an exercise program – either at home or at the Study Site facility gym. The level of effort between the two groups is the same. There is a small risk that exercise may make your muscles sore or increase fatigue, or that you might fall if you do not take precautions to prevent falling. The coach will provide you with written and verbal instructions about how to prevent a fall while exercising. You will tell the coach about any recent falls that you have experienced, and discuss how to safely exercise. The coach will modify the exercises to meet your needs and ambulation level.

The risk of relapse is small. If you experience ongoing MS symptoms, we may ask you to stop participating.

All participants will answer survey questions on a computer, which poses minimal, if any, risk. You may become tired while answering these questions. You will be able to take short breaks as needed.

All participants will take two assessments that involve walking - the Timed 25 Foot Walk Test and the Six Minute Timed Walk. These assessments pose minimal risk, but may increase your fatigue. Trained clinicians will conduct these assessments and you will be asked to walk at a pace comfortable for you.

Participating in this study involves a small risk of loss of confidentiality. Research staff and clinicians will keep your information confidential. You will be given a study ID number. All the data that you provide will be linked to this study ID number and not your name or personal contact information. When we write reports of the findings, we will not include any names or personal identifying information. We will keep all personal contact information in password protected computer files, or in locked cabinets.

## Research-Related Injury

If you experience any illness or injury as a direct result of the exercise program or assessments, treatment will be available through Study Site. The Principal Investigators and the Study Site have no provisions to pay for injury-related costs that result from participation in this study.

## Benefits

Your participation in this study may benefit you by introducing you to a new treatment. You may experience positive changes in fatigue and mobility levels.

Upon completion of the study, you will be referred back to the physician and rehabilitation team or health and wellness program to continue and follow up as desired. Outcomes from the study will be shared with the clinical team if you would like, to guide further exercise and rehabilitation choices.

The results of this research study will help us understand how people with MS who have walking difficulties respond to exercise. We will share the findings widely, including to the community of people with MS, health care providers, payers, and exercise specialists.

## Alternatives

There are no other alternatives to this study at this time.

## Confidentiality

Certain offices and people other than the researchers may look at your study records. These offices may include the Shepherd Center Research Review Committee. Shepherd Center employees overseeing proper study conduct may look at your study records. Study funders may also look at your study records. Shepherd will keep any research records we produce private to the extent that the law requires us to do so. Where possible, we will use a study identification number, not your name, on study records. Your name and other facts that might identify you will not appear when we present this study or publish its results.

To advance science, medicine, and public health, we will share information about you from this research study with other researchers, but **only after personal information that may identify you has been removed**. We will remove your name, address, and study ID number, as well as other data that could identify you. If you would like more details about the kind of information that we remove from our files, we are happy to provide this upon request. The remaining information can be combined with other people's data to help researchers understand how exercise effects people with MS. We will do everything we can to protect your privacy before sharing your de-identified data with other researchers but, despite best efforts, there is still a very small chance that you could be re-identified. To minimize this risk, we will follow all relevant data protection laws.

If, at any point during or after this study, you think that you may have been re-identified, please contact us and let us know. Because we remove your contact information from the files that we share, we will not have a way to contact you individually.

If you are placed in the Telerehab program, we will share your name and contact information with the University of Alabama so that they can contact you with information about the program. The University of Alabama will not receive your answers to the surveys and assessments you will take. The University of Alabama will not share your contact information with any entities outside the research team.

Study records can be opened by court order or produced in response to a subpoena or a request for production of documents unless a Certificate of Confidentiality is in place for this study.

The researchers will review the results of study tests and procedures only for the research. The researchers will **not** be looking at these results to make decisions about your personal health or treatment.

Data collected is stored in a commercial-grade, cloud-based, HIPAA compliant, secure data center. Data is backed up daily. Offsite backups may be held by a third party to guard against data loss.

Appropriate security measures minimize risks such as loss of confidentiality, identity theft, electronic fraud/security breaches, electronic monitoring, stalking or bullying, hacking, and phishing. Only authorized personnel can access the data center. All data transmission (uploading and downloading) occurs over secure, encrypted channels.

Participants will have individual accounts with unique usernames and passwords. Identifiers will be stored separately from other data types to protect the privacy of individual participants. Data will be de-identified when viewed by anyone but the participants themselves and authorized study staff. We will legally require anyone accessing participant-contributed data to agree not to attempt to learn the identity of any participant, or present or publish data in which an individual can be identified.

## Cost

There are no costs associated with your participation in this study.

## Compensation

You will not be charged for your participation in this study. You will receive $25 for each assessment that requires you to travel to the Study Site.

## Voluntary Participation/Withdrawal

You can withdraw your consent at any point in this study, without penalty and with no effect on your treatment at the Study Site.

## Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you rights related to your Protected Health Information. Protected health information is any information about your health status, provision of health care, or payment for health care that is created or collected by a "Covered Entity," and can be linked to a specific individual. Shepherd Center, the lead site for the study, is a Covered Entity. You have the right to know who can get your protected health information and why. Researchers and providers must get your authorization (permission) to use or release any protected health information that might identify you.

We use the term “researchers and providers” below to include the group of people who may get personal information about you.

*What information may be used and given to others?*

If you choose to be in this study, the researchers and providers will gather personal information about you. The researchers may also get information about your health including:

- Medical and research records identifying you and describing your medical condition
- Records about phone calls
- Records about your study visits
- Exercise logs and questionnaires
- Records about medications

*Who might get this information?*

The researchers or providers may give information about you and your health, which might identify you, to a third party including the following:

- Shepherd Center Research Review Committee
- Other parties as required by law

*How will this information be used?*

We will use this information to determine your appropriateness and safety for this study, and for data analysis.

*Is my health information protected after it has been given to others?*

We will keep all information that identifies you separate from the study data. We will assign you a unique study ID number. We will use this ID number, not your name, on all your study data records. We will password protect the computer file that links your personally identifiable information to your study ID number. We will keep any paper files with identifying information in locked cabinets. These files will only be available to the research staff. When we analyze the data that we collect from you, it will not be linked to your name or other identifying information. We believe these precautions eliminate any risks to confidentiality.

*What if I decide not to give permission to use and give out my health information?*

If you decide not to give permission to use your protected health information, you will not be enrolled in the study, but there will be no negative effects on you. You will still be considered for future projects at Study Site, and your treatment will not be affected.

*May I withdraw or revoke (cancel) my permission?*

You have the right to revoke this authorization and can withdraw your permission for us to use your information for this study. To revoke permission, write to the Principal Investigator listed on page one of the research consent form. If you write to the Principal Investigator, the use and disclosure of your protected health information will stop as of the date she receives your request. However, the Principal Investigator can use and disclose information collected before the date of the letter, or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with Study Site.

*May I review or copy the information obtained from me or created about me?*

While this study is in progress, you will not have access to medical information about you that is related to the study. After the study is completed and the results have been analyzed, you will have access to any medical information collected about you in the study.

## Source of Funding

Funding for this research is provided by the Patient-Centered Outcomes Research Institute (PCORI).

## Research Questions

If you have any questions about this study, or any complaints regarding this study, please contact: Deborah Backus, PT, PhD, Director of MS Research, Shepherd Center, at 404–350–7599. If you have concerns about how research is being conducted at Shepherd Center, or about your rights as a research participant, you may contact Michael L. Jones at 404-350-7595.

***This section intentionally left blank***

**SHEPHERD CENTER**
**RESEARCH PATIENT INFORMATION AND CONSENT FORM WITH AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION**

**PROTOCOL#: 738: Comparative Effectiveness of an Exercise Intervention Delivered via Telerehabilitation and Conventional Mode of Delivery**

**Consent Statement:** I will not be charged for my participation in this study. I will receive $25 for each assessment that requires me to travel to the Study Site. While no direct benefits to me are to be expected from this study, the results will be made available to my doctors. I will not be personally identified if the results of this study are published, and my participation will be kept confidential. I may withdraw from this study at any time. Withdrawing from the study will not affect any other medical care to which I am otherwise legally entitled.

**I have read this document and it has been explained to me. I have had an opportunity to ask questions and they have been answered to my satisfaction.**

**Participant Name:** _____
(Block letters)
**Signature:**_____**Date:**_____
(to be completed by subject at time of consent)

---

***Person who conducted the Informed Consent discussion:** I confirm that I have personally explained the nature, purpose, duration, and foreseeable effects of the study to the subject named above.

**Name:**_____
(Block letters)
**Signature:**_____**Date:** _____

----------**Use the following only if applicable**
----------*If this consent form is read to the patient because the patient (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the *participant* (or the *participant*'s legally authorized representative). The *participant* (or the *participant*'s legally authorized representative) freely consented to participate in the research registry.

_____ _____
Signature of Impartial Witness Date

**Note:** This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling patients who do not speak English.