

Official Title: The Role of Aging and Individual Variation in Exercise Training Responsiveness

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Consent to Participate in a Research Study
STRRIDE IV Pilot Study

CONCISE SUMMARY

The purpose of this study is to determine the feasibility of conducting a large-scale “legacy” exercise trial which would aim to evaluate the effects of aging on various health parameters in response to exercise. Findings may help guide personalized exercise medicine to optimize health and well-being in the aging population.

Participants in this study will complete 7 on-site study visits and a 6-month supervised exercise program. Assessments include the following:

- Study questionnaires
- Height, weight, and vital signs
- Blood draw (for screening)
- Oral glucose tolerance test with blood samples collected through an IV
- Body composition (BODPOD and waist circumference)
- Strength tests
- Cardiopulmonary exercise test
- Physical function tests

Your study participation will last approximately 8-9 months.

The risks of blood draw and IV placement include momentary discomfort, bleeding, bruising, inflammation, infection, and/or fainting. The risks of exercise training and testing include fainting, falling, irregular heartbeat, wheezing and shortness of breath, and very rarely, heart attack or death (less than 1 in 10,000 cases).

If you want to learn more about this study, please continue reading below.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Leanna M. Ross, PhD is the Principal Investigator conducting the study. This study is sponsored by a grant through the Duke Claude D. Pepper Older Americans Independence Center. The National Institutes of Health



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(NIH), the Duke School of Medicine, and the Duke Department of Medicine have contributed funding. Funding for the study will pay for a portion of Dr. Ross' salary and for that of the research team members.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. William E. Kraus and Dr. Kim M. Huffman will be your doctors for the study. They will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this study because you participated in the STRIDE-PD study. This pilot study is designed to determine the feasibility of conducting a large-scale "legacy" exercise trial which would also enroll former STRIDE participants and a second age-matched cohort of older adults who have not undergone recent structured exercise. The larger study would aim to evaluate the effects of aging on various health parameters in response to exercise. Findings may help guide personalized exercise medicine to optimize health and well-being in the aging population.

Up to 8 people will take part in this pilot study at Duke.

WHAT IS INVOLVED IN THIS STUDY?

Participants in this research study will be asked to complete: a consent visit that will take place remotely via ZOOM or in-person; a screening visit; assessment visits at three study timepoints (baseline, early-intervention, and end of study); and supervised exercise training sessions over the course of the 6-month intervention. All in-person study activities, including assessment visits and supervised exercise training, will occur at the Duke Center for Living campus.

You will need to use your own smartphone or tablet to download and use two mobile applications: Garmin Connect and Labfront.

Schedule of Visits

Consent (~1 hour): The consent visit will take place remotely via ZOOM or on-site at the Duke Center for Living campus. If you agree to participate in this study, you will be asked to sign and date this consent form before any research activities take place.

After the consent visit, you will be provided with a link to a series of online questionnaires to complete prior to your initial study visits.

Visit 1 – Screening (~45 minutes): To prepare for this visit, we will ask that you drink plenty of water and take any medications as usual.

During this visit, you will undergo the following:

- Measurement of height and weight
- Measurement of resting blood pressure and heart rate



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- A blood draw (less than 1 teaspoon) to measure current thyroid stimulating hormone (TSH) levels to confirm eligibility

Visit 2 – Baseline (~1 hour): To prepare for this visit, we will ask that you avoid eating a heavy meal within 2 hours of the visit and take any medications as usual.

During this visit you will complete a maximal cardiopulmonary exercise test. This test involves exercising on a treadmill to maximal effort, during which we will measure your breathing and how much oxygen your body uses. Your electrocardiogram (ECG), blood pressure, and perceived exertion (how hard you feel you are working) will also be monitored throughout this test by trained personnel.

Visit 3 – Baseline (~4.5 hours): To prepare for this visit, you will need to fast for 10 hours (nothing to eat or drink, except water) before your visit. Please take any daily medications as usual.

During this visit, you will undergo the following:

- Measurement of resting blood pressure and heart rate
- 2-hour oral glucose tolerance test
- Body composition (BODPOD and waist circumference) assessments
- Strength testing
- Receive a physical activity monitor (looks like a wrist watch)

An oral glucose tolerance test (OGTT) is used to evaluate diabetes risk by measuring how quickly glucose is removed from the blood. An OGTT is considered to be a standard clinical procedure for those at risk for diabetes. An IV will be placed in one arm to collect blood samples. After the baseline blood sample is taken, you will drink a sugary solution followed by four more blood draws taken at specific timepoints over a 2-hour period. Some of the baseline blood sample will be used to measure your current lipid profile, hemoglobin A1c, thyroid stimulating hormone, and complete metabolic panel. The total amount of blood to be withdrawn during any one study visit is approximately 45 mL (approximately 3 tablespoons).

The BODPOD and waist circumference assessments will be used to measure your body composition. The BODPOD system uses patented air displacement plethysmography to determine percent fat and fat-free (muscle and bone) mass. The BODPOD test consists of measuring body weight using a very accurate electronic scale, and body volume, which is determined by sitting inside the closed BODPOD chamber. From these two measurements, percent body fat is calculated. You will be asked to wear spandex clothing and a swim cap, provided by the study staff, to reduce the amount of air trapped within your clothing and your hair in order to obtain accurate measurements.

The strength testing will measure your leg strength and your grip strength. For the leg strength test, you will be seated in a leg extension machine and asked to extend your knee as hard as you can. For the grip strength test, you will be asked to squeeze a hand-held device as hard as you can.

At one of your baseline visits, you will be given a physical activity monitor to wear on your wrist throughout the study. This activity monitor will capture measurements related to your daily activities, including steps, heart rate,



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and sleep. This device not only counts the number of steps you take but can also distinguish the intensity of your movement and estimate the number of calories you burn each day.

We will ask you to download the Garmin Connect and Labfront applications on your personal device so the data collected by the activity monitor can be stored and synced with the apps. The study team will provide you with study-specific login information to activate the apps, so no personal information will be used.

Intervention Period (6 months):

You will be re-assigned to one of three aerobic training programs to mirror your randomized group assignment from the original STRIDE trial:

1. *Low-amount/moderate-intensity exercise group*
2. *High-amount/moderate-intensity group*
3. *High-amount/vigorous-intensity group*

Your exercise intensity will be based on your current fitness level, and your exercise amount will match the number of weekly exercise minutes you were prescribed in the original STRIDE trial. In order to achieve your weekly exercise goal, in-person exercise training will include 3-5 sessions per week for 24 weeks total.

At three timepoints throughout the intervention, you will be asked to complete a 6-minute walk test and a brief physical function test. These assessments may take place during your scheduled exercise training sessions.

Throughout the intervention, your weight will be measured weekly. If you approach a 3% weight change from baseline, a study team dietitian will contact you to gain insight into your weight change and potentially conduct a 24-hour food recall. If you approach a 5% weight change, the study team dietitian will re-contact you to discuss weight maintenance strategies and potentially ask you to complete additional 3-day food records.

Visit 4 – Early-Intervention (~1.0 hour): To prepare for this visit, we will ask that you avoid eating a heavy meal within 2 hours of the visit and take any medications as usual.

During this visit, you will undergo the following:

- Maximal cardiopulmonary exercise test

Visit 5 – Early-Intervention (~3.5 hours): To prepare for this visit, you will need to fast for 10 hours (nothing to eat or drink, except water) before your visit. Please take any daily medications as usual.

During this visit, you will undergo the following:

- Measurement of resting blood pressure and heart rate
- 2-hour oral glucose tolerance test
- Waist circumference assessment
- Strength testing



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Visit 6 – End of Study (~1.0 hour): To prepare for this visit, we will ask that you avoid eating a heavy meal within 2 hours of the visit and take any medications as usual.

During this visit, you will undergo the following:

- Maximal cardiopulmonary exercise test

Visit 7 – End of Study (~4.5 hours): To prepare for this visit, you will need to fast for 10 hours (nothing to eat or drink, except water) before your visit. Please take any daily medications as usual.

During this visit, you will undergo the following:

- Measurement of resting blood pressure and heart rate
- 2-hour oral glucose tolerance test
- Body composition (BODPOD and waist circumference) assessments
- Strength testing

You will be asked to complete study questionnaires related to your physical activity, dietary intake, and quality of life at all three study timepoints.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study may last 8-9 months, depending on schedule availability. You can stop participating at any time without penalty.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You may discuss these with the study doctor and your regular health care provider if you choose.

Risks of Maximal Cardiopulmonary Exercise Test: The exercise test will be performed on a treadmill with the amount of effort increasing gradually. This increase in effort will continue until the limits of fatigue, shortness of breath, chest discomfort and/or other symptoms are such that would indicate the test to be stopped. There exists the possibility of certain changes occurring during the test. They include abnormal blood pressure, fainting, inappropriate heart rate response, and the extremely rare instance of a cardiac event, such as a stroke or heart attack. Emergency equipment is available and trained personnel are monitoring the test if any of these unusual situations arise.

Risks of Exercise Training: Participation in an exercise program may result in muscle, bone and/or joint soreness, discomfort and/or injury. There is also the risk of falling.

Risks of Blood Draw / IV Placement: The potential risks from blood draw and IV placement include momentary discomfort, bleeding, bruising, inflammation, and rarely infection or fainting, although unlikely.

Risks of BODPOD: This test may not be comfortable for anyone who has felt claustrophobic (uncomfortable in small spaces), but is generally well tolerated.



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Unforeseeable Risks: There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will be no direct medical benefit to you. However, access to the exercise program may offer potential health benefits, and the results of the blood tests, exercise stress tests, and body composition assessments may provide useful information about your health. If you choose, the results of your study tests will be provided to you and you may decide to add these results to your personal health records.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System Institutional Review Board, NIH, and the Duke Clinical Quality Management Program (CQMP). If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you may be asked to have certain tests and/or procedures performed. Results of tests are obtained solely for this research study and therefore will not be included in your medical record.

The study results will be retained in your research record for at least seven years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.



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There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

As a participant in this study, you may be asked if you would be willing to have some of your test results from this study included in a separate data repository. If you agree to include your data, you will be asked to sign a separate consent form. Your willingness to include your data in this separate repository will not affect your participation in this study.

If you choose to be in this study, data collected from you that can be used for future research will be stored long-term in a repository following the completion of the study. Any personal information that could identify you will be removed or changed before files are stored in this repository for use by other researchers or results are made public. The removal of this information allows your data to be used without anyone knowing which person in the study it comes from.

Data Privacy/Security Risks of Mobile Apps:

The data collected via the Garmin wristband activity monitor will be stored on your personal smartphone or tablet and uploaded to the server of the Garmin Connect and Labfront mobile applications. Data will also be stored on the Garmin activity monitor itself. The study team will create a unique study-specific Duke email and an assigned unique default password for each participant. Passwords will be assigned in accordance with applicable Duke Health password security policy requirements. This email address and password will be used solely for account creation and will not be used for communication. No personal information will be used in the study-specific email or password. You will access the mobile application used in this study using the unique email address and password issued to you by the study team. We will provide you the study account information and log-in information so you can activate the app on your phone or tablet. During the study, the study team will have access to your study-specific email and password as well as the information maintained in the Garmin Connect and Labfront accounts in order to monitor your data collected. For security purposes, this information, including



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the unique default password, should not be used for any other account. At the end of your participation in the study, we will stop collecting your activity data and you will be provided instructions on how to log out of all study accounts.

Information collected by mobile applications or 'apps' is subject to their terms of use, and end user license agreements. You are encouraged to review the Garmin Connect and Labfront Terms of Use and End User License Agreement prior to using the mobile applications. By logging into your study account, you are agreeing to abide by these guidelines. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait to use the device until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Because email and text do not provide a completely secure and confidential means of communication, please do not use email or text if you wish to keep your communication private. Instead, call the study staff member to speak with them directly.

WILL IT COST ME ANYTHING TO BE IN THE STUDY?

There will be no costs to you for participating in this study. You and your insurance company will not be billed for your participation. Any other necessary therapies, tests, or additional lab work that is not study related will not be paid for by the study and will be charged to you or your insurance. You or your insurance provider will be responsible for all costs related to your normal medical care.



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WILL I BE PAID TO BE IN THE STUDY?

You will receive \$100 for the completion of all assessments associated with each study timepoint (baseline, early-intervention, and end of study), for up to \$300 for your expenses related to your participation (parking, gas, and time). You will only be paid for the timepoints you complete, and you must complete both visits associated with each time point in order to receive \$100. Upon completion of the study, you will also be able to keep the physical activity monitor for your personal use.

Payment for participation in research is considered taxable income and Duke University is required in many cases to report this information to the Internal Revenue Service (IRS).

Duke University requires that you provide your name, mailing address, and social security number for this tax reporting purpose before payment can be issued. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

Research subject payments to a non-employee of Duke University adding up to \$600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

Research participant compensation made to a Duke University employee at any time during the calendar year will result in a 1099 (Miscellaneous Income) form being issued to the employee and a copy sent to the IRS regardless of the total amount paid.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or a research-related injury, contact Dr. Huffman at 919-668-1644 during regular business hours and at 919-308-4236 after hours and on weekends and holidays.

WHAT IF I WANT TO WITHDRAW FROM THE STUDY?

If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Ross in writing and let her know that you are withdrawing from the study. Her mailing address is:

Leanna Ross, PhD
Box 102903
Duke University Medical Center



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Durham, NC 27710

Your study doctor may decide to take you off this study if they determine that it is no longer in your best interest to continue.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

A description of this clinical trial will be available on <https://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.

Your blood samples and data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

You will not be compensated for the use of your data and samples other than what is described in this consent form.

WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Ross at 919-660-6688 during regular business hours, after hours, or on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research



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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Participant

Date

Time

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Time