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Improving Exercise Capacity with a Tailored Physical Activity Intervention in Lymphoma and Breast Cancer Patients Undergoing Treatment

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Improving Exercise Capacity with a Tailored Physical Activity Intervention in Lymphoma and Breast Cancer Patients Undergoing Treatment

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ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to test whether participating in either a physical activity intervention that initiates before, during or soon after you receive treatment for lymphoma/breast cancer or a series of educational classes will help to preserve exercise capability, heart function, brain-based activities (like memory), and your quality of life. You are being asked to participate in this study because you have been diagnosed with lymphoma or breast cancer and may meet the study entry requirements.

What will happen if I participate?

You will be randomly assigned (like the flip of a coin) to receive either a healthy living education intervention or a moderate intensity physical activity intervention that includes exercise sessions that are supervised to begin with and then unsupervised in the home setting. If you are unable to travel to a supervised setting you can receive most parts of the intervention in the home after a 1-2 week introduction. You have a 2 out of 3 chance of being assigned to physical activity sessions, and a 1 out of 3 chance of receiving the healthy living workshops.

In this study, you may be asked to do the following things:

1. At each visit, you may be asked to undergo screening questions and tests for COVID-19 as per standard protocol at VCU Health, which may include answering questions about your health, measuring your temperature, or having a nasopharyngeal test performed to detect the presence of SARS-CoV2 virus. You will not be able to participate in some testing procedures if you have been recently affected by COVID-19 in the prior 60 days or you have been in close contact with a person affected by COVID-19 in the prior 21 days.
2. Participate either in a Healthy Living Intervention (HLI) - health workshop with attendance required 1-2 times per month or participate in a Physical Activity Intervention (PAI) - exercise training sessions offered each week (M,W, & F) in supervised sessions with an additional 1-2 sessions required per week at home. Alternatively, you can receive a home-based intervention, where all sessions are completed remotely. You will still have regular contact with interventionists by video or phone call.
3. A cardiopulmonary exercise test performed in an MRI scanning facility.
4. Complete some basic tests evaluating your capacity to perform everyday functional tasks (e.g. balancing, stand from a seated position, walking).
5. Questions that ask you about your quality of life.
6. Questions that test your cognitive or brain function for things like memory, recognition of numbers, etc.
7. A blood draw.
8. You will be asked to wear an Actigraph or Fitbit, or both
9. Give permission for the researchers to collect information about care received for other conditions (E.g. diabetes, high blood pressure or surgical procedures) from your medical records.

Your participation in this study will last 6 months. Approximately 18 individuals will participate in this study.

This study will not use your samples to examine or measure all or part of your DNA.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. You should discuss the risk of being in this study with the study staff. We want you to know about a few risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
1. Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue. 2. Some subjects experience discomfort associated with enclosed spaces during MRI scanning. 3. There may be some risks that the study doctors do not know about yet, so we will let you know of any new findings. 4. Blood draws may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn. 5. The study questionnaires ask questions that may be sensitive in nature and may make you feel uncomfortable. 6. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.	1. The exercise test could result in findings that might be helpful (for example, early detection of a particular condition). 2. Results from this study could provide additional information about your cardiovascular health that could be accessed by your primary care physician to better manage your care. 3. This study is not likely to help you directly. However, the information from this research study may lead to a better treatment in the future for people with disease name.
If willing to attend in-person study visit and complete COVID testing	
7. A COVID-19 (coronavirus) test can be an uncomfortable procedure. This test typically involves the use of a nasal swab.	4. Determining whether you have been exposed to and carry the COVID-19 virus is important for your own safety and that of other patients and staff at MCV, Massey Cancer Center and VCU.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

At your first visit (Baseline visit-day 1), which may be in person or via video conferencing, we will verify your medical history, current medications, identify any illness or injury that would prevent you completing an MRI or exercise testing, and answer any questions you may have about the study**.** You may also complete the following tests, depending on whether you are comfortable with coming into the hospital and being screened for COVID-19:

1. A scan in an MRI machine (if willing to come to MCV – North Hospital).
2. A cardiopulmonary exercise test performed on a treadmill (if willing to have a COVID-19 test).
3. Home-based assessments of balance, strength and physical function and walking.
4. Questions that ask you about your quality of life such as regarding your experience of physical function, social wellbeing, fatigue and other symptoms.
5. A blood draw (approximately 5 teaspoons) This will be done at a routine clinical visit or if you are willing to come to the hospital for the cardiopulmonary exercise test.

Do you agree to attend an in-person study visit at the North Hospital?

[ ] Yes **[ ]** No

Are you willing to undergo testing for COVID-19 within 2 days of your hospital visit?

[ ] Yes **[ ]** No

Approximately 1 week later, at baseline visit-day 2, you will complete a second round of testing and find out your group assignment. You will complete the following tests:

1. Questions that test your cognitive or brain function for things like memory, recognition of numbers, etc.

If you qualify for the study, you will be randomly assigned (like the flip of a coin) to receive either a healthy living education intervention or a moderate intensity physical activity intervention that includes exercise sessions that are supervised to begin with and then unsupervised in the home setting. If you are unable to travel to a supervised setting, you can receive a home-based intervention after a 1-2 week introduction. You have a 2 out of 3 chance of being assigned to physical activity sessions, and a 1 out of 3 chance of receiving the healthy living workshops.

The study staff who examine your results will not know which intervention you are receiving. This is called blinding, and it is done so that a fair evaluation of results may be made.

You will repeat baseline tests at 3 and 6 months follow up visits. These visits will also occur over two days approximately 1 week apart.

You will also be asked about your health since the last visit. Finally, you may be asked to participate in a 30-minute telephone interview that will ask you about you experiences as a part of this study. You will be asked to describe what you found difficult about being a participant in this study and what you liked about being a participant on this study. Your answers and the interview will be recorded, but your responses will be anonymous and only used to improve the interventions for future research subjects.

The investigators will also collect information from your medical records to track any cardiovascular health issues you may experience. Medical record information will be collected during your participation in the study and for 5 years after you have completed the study.

Healthy Living Intervention (HLI):
Individuals in this group will come to a centralized meeting location to participate in organized health workshops. Each session will last 60 minutes. Session attendance will be required two times per month over the 6 months. If you cannot attend workshops in person, you will have the option to attend health workshops via video conferencing software or telephone. Make up sessions either in person or over the telephone will be offered for those participants who must miss a group session. We may contact you via telephone 1-2 times a month in addition to regularly scheduled sessions.

Session Content: Introduction and Review past material (10 mins); Interactive Healthy Living Presentation (30 mins); Short instructor-led program of upper body stretching exercises (10 mins); Wrap-Up, Questions and Promotion of next Workshop (10 mins).

The Healthy Living presentations will be interactive and will provide useful information on such topics as proper nutrition, management of stress, and sleep practices. Experts across a broad range of relevant topics will also be brought in to give guest lectures over the course of the 6 months. Participants will be asked to complete homework assignments, review past topics, and engage in small group discussions to increase active involvement in this study arm. The final component of the workshop, the upper body stretching component, will be performed at each visit.

Physical Activity Intervention (PAI):

The PAI will be performed at the Kinesiology and Health Sciences Research Center to begin with, near the Monroe Campus of Virginia Commonwealth University (VCU), and then other physical rehabilitation facilities (Sheltering Arms) in your community with the supervision of a clinical exercise physiologist. Center-based Patient PAI sessions will be offered each week (M, W, & F). Participants will have the ability to participate in one to two training sessions per week and 1-2 sessions per week at home. Each Patient PAI session will consist of a slow (15min) aerobic warm-up; 20 minutes of strength training; 15 minutes of progressive intensity aerobic exercise (AE); followed by 10 minutes cool-down by stretching/toning with elastic bands similar to those recommended by the American Cancer Society. For participants who cannot travel to supervised sessions, we will provide you with the same initiation sessions at the Kinesiology and Health Sciences Research Center, following which you will be provided with equipment and instructions for performing exercise in your home setting. In addition, we will provide regular opportunities to contact with the exercise physiologists via video calling technology such as Zoom/Skype or Facetime.

The mode of activity for the AE sessions will be over-ground walking and/or stationary cycling. This approach adheres to the principle of progressive intensity and is designed to increase exercise capacity outcomes (peak VO2 peak and 6min walk distance), yet also permit individual "tailoring" based on each participant's daily perceived level of fatigue and disease/treatment related symptoms. Each session is progressively modified with regard to the intensity and duration along with appropriate rest and recovery sessions.

In addition, participants in supervised exercise will be encouraged to accumulate 150 minutes (~30 minutes day) of moderate-light intensity physical activity per week outside the program facility. This can be achieved through a variety of domestic and recreational activities performed at home. The daily and weekly targets for physical activity will be self-monitored by the participant and validated weekly by the intervention staff from the objective data obtained by the wrist-worn Fitbit and Actigraph activity monitors. An Actigraph monitor is a small, wrist-sized device that continuously measures activity or movement.

To enhance safety, each subject will be instructed to participate at an individually prescribed level of exertion, report any symptoms or problems they might encounter during physical activity, and to rest as needed. The interventionist will take time to communicate with participants during the center-based and during home-based AE sessions in order to determine whether physical activity prescriptions are appropriate, to ask how participants are feeling, and to answer questions regarding the physical activity prescription.

We can send important medical findings from your study tests/exams to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes **[ ]** No

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Risks of Exercise Test

A small chance exists that the exercise test could lead to symptoms of heart disease or injury. About 1 in every 10,000 patients with heart disease dies during an exercise test, and serious complications such as heart attack, prolonged chest pain or serious heart rhythm problems can happen in approximately 4 of every 10,000 participants. During the exercise test, there is a chance you could lose your balance, trip, or fall. To minimize this risk, trained staff will ensure that the treadmill is free from obstruction and remain nearby. As well, the exercise test could result in findings that might be helpful (for example, early detection of a particular condition) or troublesome (for example, causing you worry, involving additional and perhaps costly testing that may or may not benefit your health).

Risks of MRI Scans

MRI scans are not associated with any known side effects. Some subjects experience discomfort associated with enclosed spaces during MRI scanning. All standards of care used to monitor for any potential side effects that are used for clinical MRI facility today will be implemented and the exercise test will be carefully monitored by a cardiologist and exercise physiologist.

Risks of Blood Draws

You may experience discomfort, bruising and/or bleeding where the needle is inserted during the blood draw. Occasionally some people become dizzy, lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia). You should not donate blood more than 2 times per week and no more than approximately one pint (about 500 ml) of blood in an eight-week period.

Reproductive Risks

As the study procedures might injure an unborn child, pregnant women may not participate. Women who might become pregnant should use a medically accepted form of birth control

such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a woman become pregnant there is a risk of injury to an unborn child.

Non-Physical Risks
Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Risks of Surveys and Questionnaires
Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.

Risks of Providing Confidential Information
In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Unknown or Unforeseeable Risks
The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study procedures related directly to the study, will be paid for by the study.
Participants who are randomized into the “healthy Living Intervention” will be provided an Actigraph at no charge to use during their participation in the study. Participants who are randomized into the “Physical Activity Intervention” will be provided a Fitbit and Actigraph at no charge to use during their participation in the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. You will not be specifically directed to undergo additional testing by the care team. However, if you are found to have a serious condition during your participation on this study, the care team may advise you to seek further care including further procedures, which will be for your own responsibility.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

Parking validation will be provided for some study-related visits. You will not receive any monetary benefit for your participation in this study.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third-party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety
- you are found to not be eligible for the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System

It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the study will be included in the record. This information is protected just as any of your other health records are protected.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you. Once the study has been completed, we will send you a summary of all the results of the study and what they mean.

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 Website will include a summary of the results. You can search this Web site at any time. The deidentified data produced in this study may also be shared with a funding agency (e.g. NIH), used to produce research manuscripts, published on an open science website, presented at research conferences and used for educational training at VCU. There is no link between you the research participant and the data. After a period of approximately 5 years we will destroy any data records from this study including audio recordings from qualitative interviews.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☒ Complete health record ☒ Diagnosis & treatment codes ☒ Discharge summary

☒ History and physical exam ☒ Consultation reports ☒ Progress notes
☒ Laboratory test results ☒ X-ray reports ☒ X-ray films / images

Who will use or share protected health information about me?
VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Data Coordinators
- Research Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at

Alexander R. Lucas Ph.D.
Virginia Commonwealth University, School of Medicine
Department of Health Behavior and Policy
PO Box 980149
Richmond, VA 23298

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Alexander R. Lucas Ph.D.
Phone: (804) 628-6610
Alexander.Lucas@vcuhealth.org

and/or

W. Gregory Hundley, MD
Phone: (804) 628-6611
Greg.Hundley@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237)."

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal/Sub-Investigator Signature (if different from above)	_____ Date