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10-AUG-2023

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NCT03741335

OFFICIAL STUDY TITLE:

Group Exercise Training for Fall Prevention and Functional Improvements during and after Treatment for Prostate Cancer

INVESTIGATOR NAME:

Kerri Winters-Stone

ORGANIZATION:

Oregon Health & Science University Knight Cancer Institute



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OHSU Knight Cancer Institute Consent and Authorization Form- REMOTE

Title: GET FIT Prostate

Funded by: National Institutes of Health (NIH)

Conflict of Interest Statement: Dr. Fay Horak has a financial interest in APDM, a company involved in this study. The nature of this financial interest and the design of the study have been reviewed by two committees at OHSU. They have put in place a plan to make sure this research study is not affected by the financial interest. If you would like more information, you may contact the OHSU Research Integrity Office at (503) 494-7887.

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STUDY CONTACT INFORMATION

Purpose	Role	Contact Name	Contact Phone Number	Email
For medical questions about the study	Principal Investigator	Kerri Winters-Stone, PhD	503-494-0813	wintersk@ohsu.edu
For non-medical questions about the study	Lab Manager	Carolyn Guidarelli	503-346-0307	borsch@ohsu.edu
For questions about research in general	Ethics Committee	ORIO	503-494-7887	irb@ohsu.edu
For 24-hour medical emergencies	911	Emergency Dispatch	911	
	Oncologist On-Call	OHSU Operator	503-494-8311	

INTRODUCTION

WHAT IS THE USUAL APPROACH TO MY CANCER?

You are being asked to take part in this study because you are either currently being treated or have been treated with androgen deprivation therapy (ADT).

Treatments for prostate cancer can cause side effects such as fatigue, muscle loss, and weakness which can increase the risk of falls and frailty. People who do not take part in this study may receive recommendations, such as encouragement to exercise, and/or ways to adjust their daily activities to help combat some of the physical side effects of cancer treatment.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to take part in a different study, if one is available

PURPOSE

WHY IS THIS STUDY BEING DONE?



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The purpose of this study is to compare physical and quality of life benefits, including falls, physical function, and mood, of three different types of exercise – functional balance (similar to “tai chi”) versus functional strength versus functional mobility –for prostate cancer survivors exposed to ADT.

We are asking you to provide information for a data bank, also called a repository. This information will be stored indefinitely and may be used and disclosed in the future for research.

This is a clinical trial, a type of research study. Medical personnel who carry out research studies are called “investigators.” The investigator will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You can discuss your decision with your friends and family. You can also discuss it with your health care team or another doctor. If you have any questions, ask the investigator.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

As many as 360 men will take part in this study which will be conducted at Oregon Health & Science University (OHSU).

PROCEDURES

WHAT ARE THE STUDY GROUPS?

You will be randomized into one of three study groups.

1. Functional balance (like “tai chi”)
2. Functional strength
3. Functional mobility

“Randomization” means you will be put into a group by chance. Neither you nor the investigator can choose the group you will be in. You have an equal chance of being placed in any of the three groups.

Participants will be asked to exercise remotely (e.g., at home) using videoconferencing software. The necessary exercise equipment and a webcam will be provided, if needed, and we will ask that it be returned at the end of study. You will receive written and verbal instructions for installing and using videoconferencing software. During these web-based, group video conferences, the exercise instructors will observe and instruct participants.



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HOW LONG WILL I BE IN THIS STUDY?

You will be in the study for about 12 months.

WHAT TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

Before you begin the study:

If you are interested in participating, you will be asked a few questions regarding your cancer history, current physical activity, and fall history. We will also request medical clearance for you to participate in exercise training from your doctor before exercise class starts. You will next be scheduled to complete a series of screening assessments (see below) with a Research Assistant as part of the baseline assessment visit.

Baseline assessment visit:

- You will be asked to complete a set of questionnaires about your cancer and health history, current medications, current physical activity, and quality of life. Some of this information will be used to help determine your eligibility.
- A Research Assistant will guide you through a series of screening activities. These activities include rising and sitting from a chair five times as quickly as you can and rising from a chair, walking about 10 feet, turning around, walking about 10 feet back to the chair, and sitting down.
- At the completion of the screening portion of the visit, we will let you know if you are eligible to continue with the remainder of the baseline testing appointment (more details below). If you are not eligible, you will be thanked for your time and provided a small remuneration for your travel.

During the study:

Participants who are randomized will be asked to complete exercise classes three times a week for one hour for the next six months. This will be completed remotely (e.g., at home) using videoconferencing software. We will contact your primary care physician to obtain clearance for you to participate in the study. Physician clearance is required to participate in the study because it will help ensure your safety to perform moderate level intensity exercise. We will collect information about your cancer diagnosis and treatment from your medical records. If you have received cancer treatment outside of OHSU, we may ask you to sign a Release of Information form in order to collect this information.

After your six months of participation in the study exercise classes this portion of the study will be complete. During the next six months of the study, you can choose whether or not to continue to exercise on your own and will not be discouraged from doing so. We will ask you to report your exercise during this time via survey at 9 months and 12 months into the study. If you have a prolonged absence during the study period you may



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not be able to re-enter the exercise class if, in the opinion of the study team, it is not appropriate for you to continue in an ongoing, progressive exercise program.

All participants will take part in a remote (e.g. at home) testing session at the beginning of the study, and at 3 months, 6 months, and 12 months into the study. The tests are described below. At each testing session, you will complete a set of questionnaires that are designed to assess your health status, physical function and physical activity habits. You may refuse to answer any question in the questionnaires. The questionnaires should take approximately one hour to complete.

For your remote testing sessions we will ask you to complete a series of physical tests described as follows:

1. You will be asked to walk at your usual walking pace for about 13 feet.
2. You will be asked to rise and sit from a chair five times as quickly as you can.
3. You will be asked to sit in a chair and reach as far as you can to the ground.
4. Try to maintain your balance while standing on the floor.

The remote physical tests together will take about 1 hour to complete.

You will be asked to fill out a survey every month for 12 months where you will describe any falls you have had and any other events that may have occurred during the previous month. At month 9 and 12 you will be asked additional questions about your physical activity habits.

This schedule lists the study procedures for remote-only participation:

Procedure	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Physical Tests - remote	X		X			X						X
Questionnaires	X		X			X			X			X
Monthly Questionnaire	X	X	X	X	X	X	X	X	X	X	X	X
Exercise Classes	X	X	X	X	X	X						
Approximate Total Time per month	14-14.5 hr	12 hr	14-14.5 hr	12 hr	12 hr	14-14.5 hr	15 min	15 min	25 min	15 min	15 min	2-2.5 hr

Some participants will be asked to complete study visits in-person at OHSU in addition to the remote testing.

During your testing sessions at OHSU we will ask you to complete a series of physical tests described as follows:

1. You will be asked to walk at your usual walking pace for about 13 feet.



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2. You will be asked to rise and sit from a chair five times as quickly as you can.
3. You will be asked to sit in a chair and reach as far as you can to the ground.
4. Try to maintain your balance while standing on the floor.
5. You will have 6 small movement sensors placed on your body using a light strap and asked to maintain your balance while standing on the floor, walking back and forth over 20 feet, counting backwards from a designated number while walking, and walk up to 6 minutes.
6. You will be asked to lie down and electrodes will be placed on your wrists and ankles which will measure the amount of lean mass in your body.
7. You will be given a DXA scan that will measure the muscle, fat, and bone content of your body. A DXA scan is a type of x-ray. You must lie still on a table for about 5 minutes during this procedure.

The in-person physical tests together will take about 1 hour to complete.

This schedule lists the study procedures for remote *and* in-person testing participation:

Procedure	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Physical Tests - remote	X		X			X						X
Physical Tests – in-person	X		X			X						X
Questionnaires	X		X			X			X			X
Monthly Questionnaire	X	X	X	X	X	X	X	X	X	X	X	X
Exercise Classes	X	X	X	X	X	X						
Approximate Total Time per month	14-15 hr	12 hr	14-15 hr	12 hr	12 hr	14-15 hr	15 min	15 min	25 min	15 min	15 min	2-3 hr

RISKS

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

As part of this study, you will be asked to complete questionnaires. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.



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There are some discomforts and risks from the remote and in-person physical tests. In order to try to minimize risks, all testing will be conducted by trained personnel. You may feel sore after the physical tests. Muscle soreness usually goes away after two or three days. You may sustain an injury during the physical testing. The risk of this is low and the researchers are trained to show you the best ways to avoid injury during the tests.

In this study you may be exposed to radiation during the DXA scans, if completing in-person visits. While no radiation dose has been determined to be entirely safe, the amount to which you will be exposed is not known to cause health problems.

As with any form of regular exercise training, the risk of injury is increased. We have taken precautions to make the exercises as safe as possible. The exercises will be led by a certified exercise professional. The study exercises have been performed before in cancer survivors as well as women aged 30-85 years who have reported no significant injuries as a result of the study.

Here are important points about how you and the investigator can make these risks less of a problem:

- Tell the investigator if you are unable to complete a test or a survey. The investigator can allow for a longer rest period during the test or reschedule it for a different day
- Tell the investigator if you are unwilling to complete a test or survey. You do not have to complete some or all tests and surveys.

Let your investigator know of any questions you have about possible side effects. You can ask the investigator questions about side effects at any time.

OHSU may provide you with a device (Chromebook) to help you access the Zoom and Webex teleconferencing tools. This device is safe to use for Zoom and Webex, however, use of the device for other purposes beyond the scope of the study may not fully protect information you choose to store on the device. In using the device you accept the risk that use of the device for other purposes could result in some an additional risk. By agreeing to use the device, you are assuming liability of that increased risk. OHSU also recommends that you lock the device when not in use. If the device were to be lost or stolen, and the device were not locked by a password, data stored on the device could be compromised.

If you are provided with a Chromebook, we will require that you sign a Device Agreement outlining your responsibilities when using the device. While the Chromebook comes with security controls in place, such as the ability to password protect your device, there is a risk, however slight, that when you use your Chromebook from your home network a third party may be able to identify your IP Address. The IP Address is the computer's general physical location, however, that IP Address does not provide any health information about you. And, the study has in place multiple security controls to protect your privacy. In participating in the



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study you understand that an IP Address is considered a HIPAA identifier, and you agree to assume the risk that your IP Address could identify your general physical location.

BENEFITS

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Participants may not benefit from participating in this study; however, their participation may contribute to knowledge used for future studies that address patients with cancer.

PRIVACY

ACCESS TO YOUR TEST RESULTS

We plan to share the results of the physical tests with you at the end of the study.

WHO WILL SEE MY MEDICAL INFORMATION?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE and the WHAT TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study, store it in a repository, and conduct future research.

We may release this information to others outside of OHSU who are involved in conducting or overseeing this research, including:

- The Food and Drug Administration (FDA)
- The Office of Human Research Protections (OHRP), a federal agency that oversees research in humans
- The National Cancer Institute (NCI)

Those listed above may also be permitted to review and copy your records, including your medical records.



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We may also share your information with other researchers, who may use it for future research studies.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers can refuse to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

However, if we learn about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, we will report that to the proper authorities.

When we send information outside of OHSU, it may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your permission.

After all of the analyses are completed using your collected data, some participant data, including your contact information, will be stored in a private locked-repository managed by Dr. Kerri Winters-Stone, the Principal Investigator of this study. A code number will be assigned to your data, as well as to information about you. Only the investigators named on this consent form will be authorized to link the code number to you. Other investigators who may receive your data for research will be given only the code number which will not identify you.

We may continue to use and disclose your information as described above indefinitely.



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PARTICIPATION

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the investigator know as soon as possible so you can stop safely. Another reason to tell your investigator that you are thinking about stopping is to discuss what testing, follow-up, or additional treatment could be most helpful for you. If you stop, you can decide whether or not to let the investigator continue to provide your medical information to the organization running the study.

The investigator will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The investigator may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

WHAT ARE MY RIGHTS IN THIS STUDY?

Your participation in this study is voluntary. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. If you have any questions, concerns, or complaints regarding this study now or in the future, contact the principal investigator listed at the beginning of the form.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team
- You want to talk to someone besides the research team
- You have questions about your rights as a research subject
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at

<https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html> or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, seven days a week).



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You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Knight Cancer Institute Clinical Trials
Attn: CRQA Assistant Director
Mail Code: KR-CRQA
3181 SW Sam Jackson Park Road
Portland, OR 97239
Email: trials@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already taken action based on your authorization.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

You will be told of any new information that might make you want to change your mind about continuing to be in the study.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study.



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You will receive compensation for the completion of each of the four study visits, consisting of physical performance assessment appointments and surveys, as listed below. If traveling to the testing site from greater than 30 miles away, you will receive added compensation at each testing time point. This compensation is determined by driving distance and will not exceed \$50 per testing time point. If you are traveling to OHSU from greater than 75 miles away, you may be provided with one night of hotel accommodations in the OHSU vicinity at each testing time point.

Study Activity	Compensation
Surveys	\$10
Physical tests – remote	\$10
Physical tests – in-person	\$15
Travel \geq 30mi from OHSU	\$25-\$50
Travel \geq 75mi from OHSU	1 hotel night

In addition, you will have the opportunity to receive up to \$50 for completion of each 3-month period of the intervention, for a maximum of \$100. The amount received will depend on the average number of exercise class sessions you attend per week. We will use the following compensation structure:

# of classes attended/12 week increment	average # of classes/week	Compensation amount
25-36	2.1-3.0	\$50.00
13-24	1.1-2.0	\$40.00
7-12	0.51-1.0	\$30.00
0-6	0.0-0.50	\$0.00

We may request your social security number in order to process any payments for participation. You will receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet.

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?



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If you believe you have been injured or harmed while participating in this research and require treatment, contact Dr. Kerri Winters-Stone at (503) 494-0813.

If you are injured or harmed by the study procedures, you will be treated. OHSU does not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

WHAT IS COMMERCIAL DEVELOPMENT AND HOW DOES IT AFFECT ME?

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHERE CAN I GET MORE INFORMATION?

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).

If you want more information about this study, ask your investigator.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

You can talk to the investigator about any questions or concerns you have about this study or to report side effects or injuries. Outside of regular clinic hours, you can speak with an oncologist on-call. Refer to the beginning of this consent form for contact names and phone numbers.



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SIGNATURE

MY SIGNATURE AGREEING TO TAKE PART IN THE STUDY

Your signature below indicates that you have read this entire form and that you agree to be in this study. We will give you a copy of this signed form.

Participant Printed Name

Participant Signature

Date/Time

Person(s) Obtaining Consent Printed Name

Person(s) Obtaining Consent Signature

Date/Time

Use of an Interpreter: Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in _____ (state language) by an individual proficient in English and _____ (state language).

If applicable:



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Print name of impartial witness: _____

Signature of impartial witness: _____ Date: _____

See the attached short form for documentation.