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Consent to participate in the
Triple-A Pilot Study: Actively intercepting ADT-induced metabolic aberrations

INVESTIGATORS:
Marian L. Neuhouser, PhD, Multiple Principal Investigator, Fred Hutchinson Cancer Center, (206) 667-4797
Jonathan Wright, MD, Multiple Principal Investigator, Veterans Affairs (VA) Puget Sound Health Care System; Fred Hutchinson Cancer Center; (206) 579-8922
Jeannette Schenk, PhD, Co-Investigator, Fred Hutchinson Cancer Center, (206) 667-6860
Sarah Altvater, MS, RD, Study Dietitian, Fred Hutchinson Cancer Center, (206) 667-7091
24 Hour Emergency Line: (206) 667-7091

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY

You are invited to participate in a research study. The purpose of this research is to test whether a diet and exercise intervention can help men manage weight and maintain health during androgen deprivation therapy (ADT) along with their radiation treatment for prostate cancer.

People who agree to join the study will be asked to attend two visits at the Fred Hutch Cancer Center over 6 months. This study involves blood and stool samples, measurements of body size and composition, questionnaires, and random assignment to either a lifestyle intervention or to control, as described below in this form.

You do not have to join this study. We will give you details about the purpose, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

WE WOULD LIKE YOU TO JOIN A RESEARCH STUDY.

The Triple-A Pilot study is a 6-month randomized controlled trial of a diet and exercise intervention in men starting androgen deprivation therapy (ADT) plus radiation therapy (RT) for prostate cancer. The purpose of this research study is to determine whether a diet and exercise intervention can promote weight maintenance and prevent metabolic changes during ADT. We will enroll 20 men with prostate cancer who are scheduled to begin treatment with anti-androgen therapy (ADT) and radiation. Half of these men will be randomly assigned to the 'Diet and Exercise' group. These men will be asked to change their diet and exercise habits. The other half of men will be assigned to a 'Control' group. These men will not be asked to change their diet or exercise habits.

WHAT RESEARCH TESTS AND PROCEDURES ARE PART OF THIS STUDY?

All participants will be asked to attend 2 study visits, at the beginning (today) and end of the study (month 6), at Fred Hutch. The following tests and procedures will be done at these visits.

- **Blood.** We will collect blood 2 times during the study – at the beginning and at 6 months (end of study). You will be asked to refrain from all foods and beverages (except non-carbonated water) for 12 hours prior to these visits. For each blood draw, we will collect approximately 2 tablespoons of blood.

- **Stool.** You will collect a small amount of stool (< 1 teaspoon) 2 times during the study – you will collect this at home prior to study visits at the beginning and at the end of the study (6 months). We will provide detailed instructions and supplies for this collection.

- **Physical Measurements.** We will collect several physical measurements during this study. *Anthropometrics.* Height will be measured at the beginning of the study only. Weight and waist circumference will be measured 2 times during the study - at the beginning and at 6 months (end of study). If you are in the diet and exercise intervention, you will also be weighed at each dietitian visit and/or exercise session.

  Dual x-ray absorptiometry (DXA). A DXA scan measuring body fat and lean mass will be completed 2 times during the study - at the beginning and at 6 months (end of study).

- **Questionnaires**. You will be asked to complete several questionnaires during this study. *Lifestyle.* This questionnaire asks about your lifestyle habits such as smoking and alcohol use and family history of prostate cancer. This questionnaire will be completed at the beginning of the study.

  Food Record. You will be asked to write down all of the foods and beverages you consume for 4 days in a food record. The food record will be completed 2 times during the study - you will record this at home prior to study visits at the beginning and at 6 months (end of study). Detailed instructions will be provided on how to complete the food record.

  Physical Activity. This questionnaire asks about different types of activity during the past month. The physical activity questionnaire will be completed 2 times during the study – at the beginning and at 6 months (end of the study).

  Quality of Life. This questionnaire asks about prostate-cancer specific quality of life and fatigue during the past month. The quality of life questionnaire will be completed 3 times during the study – at the beginning, at 3 months and at 6 months (end of study). The questionnaire at 3 months will be completed online or by mail.

  Exit Survey. This questionnaire asks about your experience participating in the study. Participants assigned to the intervention will also be asked about their experience with the intervention.

- **Study group assignment.** You will be assigned randomly (like flipping a coin) to either the 'Diet and Exercise' group or the 'Control' group. You will find out which group you are assigned to at the first study visit (today).

  Diet and Exercise Group. If you are in the diet and exercise group, you will be instructed on ways to change your diet and increase physical activity.

  Diet Instruction. You will meet with a dietitian up to 10 times during the 6-month study (once a week for 4 weeks, then once every other week for 8 weeks, then once a month for 2 months;30 to 60 minutes each session) to receive diet instruction. Dietitian meetings will take place at the Fred Hutch at times convenient for you. Some meetings may be conducted by telephone or video conference if necessary.

  Diet instruction will be based on the Dietary Approaches to Stop Hypertension (DASH) diet. This pattern is high in fruits and vegetables, lean protein and whole grains, and limits sodium and saturated

fat. During meetings with the dietitian your weight will be recorded, and the dietitian will review your progress, discuss any issues that may have arisen and provide information on how to achieve diet goals. The instruction can be tailored to any religious or cultural eating habits or dietary restrictions that you may currently follow.

Exercise Instruction. You will meet with an exercise specialist to receive one-on-one training (two times during the first two weeks; 30 to 60 minutes each session) and complete supervised exercise (once a week for up to 21 weeks; 30 to 60 minutes each session). One-on-one instruction with the exercise specialist will take place at the Fred Hutch and will be scheduled to coincide with dietitian meetings. During these sessions an exercise specialist will teach you specific strength and aerobic exercises, and provide information on how to achieve exercise goals, make active choices and stay motivated. All one-on-one training and supervised exercise sessions will take place at Fred Hutch. The exercise instruction will be tailored to your exercise preferences and capabilities.

Control Group. If you are in the Control group, you receive information on healthy lifestyle recommendations available to the general public. At the first study visit (today), the study dietitian will provide instruction on general healthy activity and dietary guidelines and will discuss the benefits of healthy weight (20-30 minutes). At the end of this six-month study you will receive the same instruction materials that were provided to the diet and exercise group.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for 6 months.

The Principal Investigators or your doctor may remove you from this study at any time. This would happen if:

- They think it is in your best interest to drop out.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

If you leave the study, your test results and information cannot be removed from the study records.

WHAT WILL MY INFORMATION AND SAMPLES BE USED FOR?

Your information, blood and stool samples will be used solely for the purposes of this study. We plan to measure markers in your blood and stool, such as cholesterol and other lipids, glucose and insulin, that may change during your prostate cancer treatment.

During this study, the researchers learn new information that may be important to your general health. This information will be shared with your preferred care provider.

We would like you to donate some of your samples for other research

After the analyses for this study, some samples may be left over. We would like you to donate leftover samples for future research.

You do not have to donate your samples for future research. You are free to say yes or no. Your regular medical care will not change. If we want to use your samples for other research or share it with other scientists for research, an ethics review committee (IRB) will review the request. The IRB will decide if we need to ask for your consent to do the research.

Your donated samples will be stored in a secure location. They will be used for research only. This research may be done by for-profit companies. Researchers will not report their results to you or your doctor. The research results will not appear in your health record. They will not affect your care.

If you donate your samples for research, you can change your mind anytime. Just call Dr. Jeannette Schenk at 206-667-6860 and tell us you do not want us to use your samples. There is no penalty for changing your mind. Your regular medical care will not change. However, if you do change your mind, we cannot return donated samples. We may be able to destroy samples we know are yours. But if they are stored or shared anonymously (without any label saying who it belongs to), we cannot destroy it. In this case it would still be used for research, but no one would know it was yours.

Read each question and think about your choice. When you decide on each question, please circle **yes** or **no**.

Do you agree to donate your samples to study cancer? (circle one) **YES** **NO** Initials: Date:

Do you agree to donate your samples to study other health problems, such as diabetes, Alzheimer's disease, or heart disease? (circle one) **YES** **NO** Initials: Date:

RISKS OF BEING IN THIS STUDY

- **Blood Draw [*all participants*].** You may experience a temporary bruise from having blood drawn. All efforts will be made to minimize this risk. You may feel lightheaded or faint when having blood drawn. If you feel faint, tell the person drawing your blood and he or she will have you lie down until the feeling goes away.

- **Stool collection [*all participants*].** Collecting may be inconvenient or uncomfortable. We will give you collection kits with everything you will need to make the collection as easy as possible.

- **DXA scan [*all participants*].** DXA delivers a small dose of radiation, which is less than the amount of radiation you would get from one day of natural background radiation, and much lower than that of a standard chest X-ray This use involves a minimal risk with no harmful health effects expected and is necessary to obtain the research information desired.
- **Burden [*all participants*].** Some participants may feel that coming to study visits (including the 'Diet and Exercise' intervention sessions) may be inconvenient or burdensome. We will make every effort to schedule these visits at times that are convenient for the participant. This includes all sessions with the study dietitian and exercise specialist. If needed, some intervention sessions can be completed remotely.
- **Exercise [*Diet and exercise group only*].** Participants may experience fatigue, muscle soreness, and possible joint or skeletal injury. These risks are reduced by proper warm-up and cool-down periods, instruction, and monitoring by a trained instructor. Risk of a more serious medical problem such as a heart attack is low, similar to that of other activities of daily living. These risks only apply to participants randomized to the intervention arm.

WHAT ARE THE BENEFITS?
We do not know if this study will benefit participants. We hope the information we learn will help people undergoing ADT treatment for prostate cancer in the future.

YOU HAVE OTHER CHOICES BESIDES THIS STUDY.
You do not have to join this study. You are free to say "yes" or "no". Your regular medical care will not change. Enrollment in this study may exclude you from other research studies.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them.

Your other choices may include:
- Exercising and changing your diet on your own.

PROTECTING YOUR PRIVACY AS AN INDIVIDUAL AND THE CONFIDENTIALITY OF YOUR PERSONAL INFORMATION
Some people or organizations may need to look at your research records for quality assurance or data analysis. They include:
- Researchers involved with this study.
- National Cancer Institute
- Fred Hutch Cancer Center Institutional Review Board (IRB). An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutch Cancer Center and University of Washington.
- US National Institutes of Health, Office for Human Research Protections (OHRP) at the US Department of Health & Human Services

We will do our best to keep the personal information in your medical and study records confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.
We could not use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:
- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.

- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

WILL YOU PAY ME TO BE IN THIS STUDY?
Participants who complete this study will receive a total of $100 to help compensate for their time and travel expenses. $25 will be paid after the first study visit and $75 dollars at the end of the study. You will be able to pick up your payment check in person at the Fred Hutch at your clinic visit or if you choose, we can send the payment to your residence via US mail.

HOW MUCH WILL THIS STUDY COST ME?
There are no costs for being in this study.

WHAT IF YOU GET SICK OR HURT AFTER YOU JOIN THE STUDY?
For a life-threatening problem, call 911 right away or seek help immediately. Contact your doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Dr. Neuhouser at 206-667-4797. If necessary, Dr. Neuhouser will refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

YOUR RIGHTS
You do not have to join this study. You are free to say "yes" or "no".

If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.

During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.

If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

A description of this clinical trial will be available on *http://www.clinicaltrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

WHO CAN I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have questions or concerns about this study, you may talk to your doctor anytime. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including emergencies, complaints and requests for information)	206-667-4797 (Dr. Marian Neuhouser, *Multiple Principal Investigator*)
If you get sick or hurt in this study	206-667-4797 (Dr. Marian Neuhouser)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)
Your bills and health insurance coverage	Please contact your insurance company or primary care physician

Consent to participate in the Triple A Pilot Study

Signature

If you have read this form (or had it read to you), asked any questions, and agree to participate, please sign:

_____ _____

Participant's Signature Date

_____

Participant's Name (Please Print)

Researcher/staff statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature / date