Prehabilitation of Veterans with Exercise and Nutrition (PREVENT)

NCT04485611

March 8, 2021

Participant Name:	**Date:**
Study Title: Prehabilitation of Veterans with Exercise and Nutrition (PREVENT)	
Principal Investigator: Atilio Barbeito, MD	**VAHCS**: Durham VAMC

OVERVIEW AND KEY INFORMATION

Please read this form carefully. You are being asked to participate in this research study because you passed our eligibility requirements and are scheduled for surgery at the Durham VA Healthcare System (Durham VA). This study is voluntary and will include only people who choose to take part. As your study doctor or study staff to discuss this consent with you, please ask him/her to explain any words or information that you do not understand. It is important that you understand the information on this form.

The purpose of this study is to determine if it is feasible to implement a prehabilitation program that includes exercise training and nutritional support for patients scheduled to undergo surgery at the Durham VA. Your participation will involve exercise training combined with nutritional support before and after your surgery. You will also be asked to complete surveys in person or over the phone and may receive automated text messages related to your individual exercise and nutritional program.

Some risks of this study include physical injury or minor discomfort from the exercise training. However, your overall participation in our study poses no cost or significant risk to you—every effort will be made to preserve your privacy and confidentiality.

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided at the Durham VAHCS or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research-related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study-related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957. There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services

provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WHY IS THIS STUDY BEING DONE?

This study is being done to determine if it is feasible to implement a prehabilitation program that includes exercise training and nutritional support for patients scheduled to undergo surgery at the Durham VA. We are especially interested in looking at how well our prehabilitaion program works for veterans living in rural areas and those with difficulties with travel to the medical center and other kinds of social support.

For this study, the difference between usual care and study procedures is the addition of an individualized exercise training program and nutritional support before and after surgery.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 24 people will be enrolled in this study at the Durham VA Health Care System.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last approximately 7 months (or 28 ± 2 weeks). Participation will begin about 21-30 days before you are scheduled for surgery, continue through your day of surgery here at the Durham VA, and end about 6 months (or 24 weeks) after discharge.

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this research study, you will be asked to sign and date this consent form.

Before Surgery

Lasts 2-4 Weeks

After you sign this consent form, you will complete a series of surveys related to your physical activity, nutrition, and quality of life. Finally, you will enroll and participate in individualized exercise and nutritional support sessions, which you will complete from home 3 times a week for up to 4 weeks (until the day of surgery).

Day of Surgery

At the hospital but before your actual surgery, you will complete a series of surveys and physical function assessments. A member of the team may also obtain your body weight and other body measurements, which will tell us about your nutritional status. Aside from that, you will not be involved in any other study events on this day.

Before Hospital Discharge

Once you are ready to be discharged from the hospital following your surgery, you will again complete a series of surveys and physical function assessments. A member of the team may also obtain your body weight and other body measurements, which will tell us about your nutritional status.

After Discharge: Phase 1

Lasts up to 6 Weeks

You will continue your exercise and nutritional support sessions from home 3 times a week. At that time, you can return to your normal diet and type of activity (or as directed by your surgical team).

After Discharge: Phase 2

Lasts up to 18 Weeks

At approximately 6 months after your surgery, you will be contacted by phone and asked to complete a last series of surveys. This marks the end of your participation in this study.

To sum up—the only differences between participating in this study and the procedures necessary for your usual medical care around the time of surgery are 1) completing surveys and 2) participating in at-home exercise and nutritional support session a few times a week. We do not anticipate your participation to increase the duration, complexity, and/or discomfort of your hospitalization. All exercise and nutritional support sessions will be performed at home with remote supervision.

Your data will not be stored and used for future studies even if identifiable information (for example your medical record number) are removed.

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WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

There are minimal risks associated with participating in our prehabilitation program. Potential risks include minor discomfort or physical injury that might occur during the exercise sessions.

There are no known physical risks associated with this study outside of those potentially encountered in daily life or when performing daily living activities. Even though participating in this research does not increase your risk of physical injury beyond those you would expect to encounter in everyday life, the events involved in this study will be closely monitored and we expect very few, if any, adverse events directly related to this study.

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. If you choose to take part in this study, you are at minimal risk of physical injury, discomfort, and loss of confidentiality. You should discuss these risks with your study doctor.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may personally benefit from taking part in this study in that the exercise and nutrition may improve your physical condition and decrease your risk of complications. Your participation may also lead to knowledge that will help people in the future. The benefit of participation in this study is in the possibility to significantly improve surgical care at the Durham VA, especially if our exercise and nutritional support program proves to work well with veterans. Furthermore, the remote care component of this program would provide prehabilitation to rural populations and those with limited support or access to transportation.

WHAT OTHER OPTIONS OR ALTERNATIVES DO I HAVE?

Taking part in this study is your choice. You may choose to not participate.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

Your information used for this study will be kept confidential as required by law. The results of this study may be used for scientific purposes or for publication, but these results will not include any information that would identify you. Your identity will not be disclosed without your consent, or

unless required by law. Your research records will be handled in accordance with requirements that guide keeping and destroying VHA records.

Hardcopy documents will be stored in folders and binders and kept inside a locked cabinet in our Anesthesia Research Office (C3011A). These are accessible to research personnel only. Electronic data will be stored on secure VA servers accessible only to study personnel. Study data will be reviewed as patients are enrolled and any member of the study team may review source documents or data at any time. Protocol deviations, data discrepancies, errors, or missing information will be resolved and/or reported per DVAHCS and IRB policy.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There are no costs to you for any of the research treatments or research testing done as part of this study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will be eligible to receive up to $200 for participation in this study -- $50 for each face-to-face visit you have with a member of the study team for answering surveys or other assessments. The first will be at the time of your preoperative visit, and another at your 6-week postoperative checkup. The others may be scheduled if the study team feels it would be better to see you in person.

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WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAHCS or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research-related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study-related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WHAT ARE MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You can choose not to be in this study, or, if you agree to be in the study, you can withdraw at any time. If you withdraw from the study, no new data about you will be collected for study purposes. We will keep and use the data that we already collected before you withdrew your consent.

If you choose not to be in the study or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

Tell the study doctor if you are thinking about stopping your participation in the study or decide to stop. If you tell researchers or the study doctor that you are thinking about stopping, discuss what follow-up care and testing could be most helpful for you.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Atilio Barbeito, the Principal Investigator for this study, may take you out of the study without your consent if it is no longer safe for you to participate in the exercise and/or nutritional support programs. The investigator may also withdraw you from the study without your consent for one or more of the following reasons: you experience serious physical injury or discomfort, your condition worsens, or your study doctor decides it is no longer in your best interest to continue in the study, or you fail to follow instructions from the investigator and/or study staff.

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

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

Results of this research will not be shared with you. The purpose of the study is to test the practicality and safety of a prehabilitation program rather than to determine if it is effective. A future study will be performed to determine whether it is effective in improving outcomes after surgery.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Atilio Barbeito at (919)-286-0411 Ext. 17-7510 during regular business hours or at (919)-636-0125 after hours. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 17-7632. If you would like to check that this study is approved by the Durham VAHCS's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 17-6926.

AFFIRMATION FROM PARTICIPANT

I have read this form, or it has been read to me. My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

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Signature of Participant **Date**

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Signature of Person Obtaining Consent **Date**

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