THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

PancStrength: Safety, feasibility, and acceptability of a tele-exercise resistance training intervention during pancreatic cancer treatment and following pancreatic cancer resection
2020-0147

Study Chair: Karen Basen-Engquist

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This study has been reviewed and approved by an Institutional Review Board (IRB -a committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to learn if real-time "tele-exercise" resistance training (training done using a tablet) may help maintain skeletal muscle, strength, physical function, and health-related quality of life in patients who are receiving chemotherapy for pancreatic cancer and patients who have previously had surgery for pancreatic cancer.

This is an investigational study.

You may be able to maintain or improve your fitness level, physical functioning, and health-related quality of life. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including the safety of home-based exercise programming and the time commitment. You may experience muscular soreness as a normal effect of resistance training.

You can read a list of potential risks below in the Possible Risks section of this consent.

You will take part in this study for about 2-3 months. However, if intolerable side effects occur, study personnel will work with you and your physician to decide if continuing the exercise program is in your best interest.

There will be no cost to you for taking part in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to participate in this study. The following screening procedures will be performed to help the study staff and doctors determine if you are eligible:

- You will have a physical exam. If you have had one recently, it may not need to be repeated
- You will complete questionnaires about your health and physical activity. These questionnaires will take you about 15 minutes to complete.
- If you can become pregnant, the study team will check your medical records to make sure you are not pregnant. If you are pregnant, you cannot take part in this study. If you become pregnant while taking part in the study, please tell the study doctor.

Study personnel and/or physicians will discuss your screening results with you. If the screening tests show that you are not eligible to participate, you will not be enrolled. Other options will be discussed with you.

Up to 75 participants will be enrolled in this study. All will take part at MD Anderson.

Baseline Visit

Before starting the exercise program, you will receive the home-based exercise equipment (a set of resistance tubes) and a computer tablet, if you do not have your own tablet or laptop. You will be given instructions and information about how to meet with your trainer over video conference, the exercises you will perform at home, and the nutrition and protein intake needed to complement the exercise program.

At this visit, you will perform baseline tests for muscular strength and endurance and aerobic fitness in the Behavioral Research and Treatment Center (BRTC) at MD Anderson. These tests will include using the following resistance training machines: leg press, chest press, leg extension, and seated row. You will also be asked to perform a 6-minute walking test to check how far you can walk in 6 minutes.

You will also repeat the screening questionnaires and complete additional questionnaires about your levels of fatigue, your health-related quality of life, your exercise motivation, possible barriers to exercise, and your social support for exercise. These will take about 45 minutes total to complete. The questionnaires can

be emailed to you so that you can complete them from home, but you must complete them before starting the exercise program.

You will have a CT scan as part of your standard care to check the status of the disease. The scan will be used in this study to measure the amount and density of the skeletal muscle in your abdomen.

You may be able to complete the baseline tests remotely without having to visit the BRTC, if you prefer this option. This can be done through video chat (such as Zoom). To complete the fitness test remotely, you will be complete a 30-second chair stand test, a 30-second arm curl test, and a 2-minute step test in which you will step in place as quickly as possible. The resistance tubes will be mailed to you directly.

Exercise Program

You will be encouraged to take part in home-based resistance training throughout 2-3 months of chemotherapy or for 2-3 months after your surgery. These sessions will be guided in real time and supervised by an exercise trainer certified by the American College of Sports Medicine. You will be encouraged to perform at least 4 resistance training sessions every 2 weeks. Each session will last about 30-45 minutes and you will rest for at least 1 calendar day between sessions and as needed due to treatment schedules. If you are too tired, busy, or prefer not to meet with your trainer for a scheduled session, your trainer will make every attempt to reschedule the session with you.

Communication with Study Staff

If you enroll in this study, study staff (including your exercise trainer) will contact you regularly to schedule exercise training sessions. You will be asked to provide your email address and/or home or mobile phone number, and you will have the option of receiving these communications by email, phone call, or text message. Your standard rates for these types of communication will apply, and MD Anderson will not be responsible for reimbursing you for these costs. Your contact information will be stored securely behind a firewall on MD Anderson servers and will only be accessible to appropriate study staff. Emails and text messages will be sent through MD Anderson's secure email services or on MD Anderson mobile devices.

Follow-up Visit

After your first 2-3 months of program participation, when you return to MD Anderson for restaging appointments, you will be asked to perform the following activities:

- If you borrowed one for this study, you will return the study tablet with video conferencing software. If the study tablet breaks, is lost, or stolen at any point during this study, please tell the study staff right away and they will send a replacement. You will not be responsible for the cost of the lost/stolen/damaged tablet.
- You will repeat the baseline tests for muscular strength and endurance and aerobic fitness.
- Your follow-up, standard of care CT scan will be used to measure the amount and density of skeletal muscle in your abdomen.

- You will repeat the baseline questionnaires. These can be emailed to you and can be completed from home. You must complete these within one week of your follow-up tests.
- If you did this study remotely (without visiting the BRTC), you will repeat the chair stand test, arm curl test, and step test that you performed at baseline. These tests will be repeated before your restaging appointment at MD Anderson.

2. POSSIBLE RISKS

While on this study, you are at risk for some side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

Resistance training may cause sore or pulled muscles, lead to respiratory or 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. If at any point supervised exercise becomes too difficult or if you think you are injured, please let the study staff know. They may request for you to come to the clinic to see how you are doing or ask you to go to your local doctor.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair. Based on your answers, if the study staff thinks it is needed, you will be asked to speak with a social worker or other certified professional for further assessment and to help with your distress.

Although every effort will be made to keep **study data** safe, there is a chance that your personal health information could be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets. Personal identifying information connected to your questionnaire answers will not be shared or published.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or The Duncan Family Institute for Cancer Prevention and Risk Assessment for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study. You will be allowed to keep your exercise equipment, but the tablet will be returned at the end of the study.

Additional Information

4. You may ask the study chair (Dr. Karen Basen-Engquist, at 713-745-3123) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, The Duncan Family Institute for Cancer Prevention and Risk Assessment, or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored by: The Duncan Family Institute for Cancer Prevention and Risk Assessment.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and The Duncan Family Institute for Cancer Prevention and Risk Assessment, and/or shared with other researchers and/or institutions for use in future research. Information may be stored indefinitely after this study is closed. **This is a required part of this study.**

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - The Duncan Family Institute for Cancer Prevention and Risk Assessment, who is a sponsor of this study, and/or any future sponsors/supporters of the study
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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 Web site at any time.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2020-0147.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)