THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

"SurgeryStrong". Preoperative strength exercise and nutrition program in patients completing neoadjuvant chemoradiation therapy for pancreatic and gastric cancer: A randomized trial testing effects on strength, fitness, health-related quality of life, and perioperative outcomes
2020-0026

Study Chair: Matthew Katz

_____ _____
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.

STUDY SUMMARY

The goal of this research study is to learn if home-based exercise and nutrition monitoring program (called Pt Pal) can help to improve overall strength in patients with pancreatic or gastric cancer who are scheduled to receive chemotherapy before standard-of-care surgery.

This is an investigational study.

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 potential expenses and time commitment.

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

You will use the exercise program during your pre-operative period, including during the time you are on other treatment before surgery. In addition, you will continue to complete questionnaires up to 6 months after your scheduled standard-of-care surgery.

However, if intolerable side effects occur or the disease appears to get worse, the study staff will decide if continuing the exercise program is in your best interest.

There is no cost to you to participate in this study.

You may choose not to take part in this study. Instead of taking part in this study, you could seek nutritional and exercise recommendations outside of this study.

1. STUDY DETAILS

Screening Tests

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

- You will have a physical exam.
- You will complete a six minute walk test. The six-minute walk test measures the distance you are able to walk over a total of six minutes on a hard, flat surface. The goal is to walk as far as possible in six minutes. You will be allowed to self-pace and rest as needed during the walk along a marked walkway.
- Your upper body and lower body strength will be measured. You will be asked to compete some strength exercises (such as a leg press, chest press, leg extensions, and so on). The study staff will demonstrate these exercises and show you how to complete them.
- You will complete questionnaires about physical activity and quality of life. These will take about 15 minutes total to complete.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups and Pt Pal App

If you are found to be eligible to take part in this study, you will be randomly assigned (as in a flip of a coin) to 1 of 2 study arms. This is done because no one knows if one study arm is better than, the same, or worse that the other group.

- If you are in Arm A, you will not take part in a monitored structured strengthening exercise and nutrition program.
- If you are in Arm B, you will take part in a monitored structured strengthening exercise and nutrition program as described below.

Up to 48 participants will be enrolled in this study. All will take part at MD Anderson.

Both you and your doctor will know which arm you are in. All participants will download the Pt Pal application (“app”) onto your smartphone or desktop web browser on your own personal device. During the study, no matter which arm you are in, you will use the Pt Pal app to track your nutrition. The information you add to the app will be monitored

by the study team. After the study ends, you will no longer receive either exercise or nutrition prescriptions. Your account will be discharged (removed) from Pt Pal, and you will no longer have access to Pt Pal.

In addition, information will be collected from your medical record during the study. This information may include demographics (such as age, sex, race, marital status, and place of residence) and information about your health (such as presence of a primary caregiver, results of routine tests, and history of side effects).

Nutrition

You will receive a nutrition consultation with a registered dietician within 7 days after enrolling in the study. You will be given nutritional guidelines and information on how many calories per day you should be consuming.

At the time of your consultation, you will complete a questionnaire about what you have eaten in the last 24 hours. After the consult, you will complete this questionnaire (diet diary) at least 1 time each week until your scheduled surgery. This will be prompted by, and completed through the Pt Pal app.

All participants will be given an immune-enhancing oral supplement called Impact Advanced Recovery. You will take this 1 time a day starting at least 5 days before your surgery.

Arm B Only

In addition to the above, you will consume a high protein snack, meal, or shake (at least 15-25 grams) within 1 hour after any strengthening exercises (described below). You will log your high protein snack, meal, or shake into Pt Pal.

Exercise

Arm A Only

If you are in Arm A, you will be encouraged to complete at least 30 minutes of moderate intensity aerobic exercise (such as brisk walking or stationary bike cycling) at least 3 times per week.

Arm B Only

You will complete a combination of at least 30 minutes of moderate intensity exercise (such as brisk walking or stationary bike cycling) at least 3 times per week.

You will also be shown how to complete strength exercises with resistance tubes/bands. You will complete these strengthening exercises at least 2 times per week, with at least 2 sets of 8-15 repetitions of the exercises you are taught. Over time, the amount of resistance may increase based on your strength. The Pt Pal app will have instructions to help you. You will be given progressive resistance tubes to complete these exercises (meaning the first set of tubes given to you will be low resistance so they are a little easier to use, but as you get stronger, you will receive higher resistance bands which may be more difficult).

Your exercise performance in Pt Pal will be reviewed by the study team weekly in order to provide recommendations for the next week. The study team will call you every week to discuss your performance and make recommendations only if there are any deficiencies in your exercise performance on Pt Pal. The calls are expected to last no more than 10-15 minutes each.

You will be asked to drink a high-protein shake/meal/snack within one hour of your strengthening exercise.

Follow-Up and Phone Calls (Arm B only)
The research team can see the information you add to the app. If they think that you need additional education or reminders about your exercise or nutrition, they will call you. Additionally, every week while you are using the Pt Pal app, the research team will call you and discuss with you goal-setting, skills and information related to physical activity, and how to overcome barriers related to food and exercise. You will also discuss your goals from last week and your goals moving forward.

Each call should last about 10-15 minutes.

Arm A and Arm B Pre-Operative Visit
About 4-6 weeks after you have been enrolled in the study, you will come to the clinic as part of your standard of care for your pre-surgery tests/procedures. At this time:

- You will have a CT scan as part of your standard of care.
- You will complete a six minute walk test.
- Your upper body and lower body strength will be measured.
- You will complete questionnaires about physical activity and quality of life.

2. POSSIBLE RISKS

While on this study, you are at risk for 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.

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. If at any point the physical activity 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.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel "closed in" while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. When a CT scan of the abdominal area is taken, material may be inserted into the rectum to better define the bowel. You will usually drink liquid to help define various abdominal organs. This may cause nausea and/or vomiting. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

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.

Data from this study may be shared with other IRB approved protocols and/or with researchers outside of MD Anderson for future research to understand pancreatic and gastric cancer and treatment.

This study may involve unpredictable risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, blood (about 1 teaspoon each time) will be drawn at your first clinic visit and then about 3-6 months after surgery for research testing related to inflammation and other markers in the blood that may be related to exercise. These tests will occur in the laboratory of Dr. Keri Schadler, an MD Anderson faculty and study collaborator. After that testing is complete, any leftover blood will be stored in Dr. Schadler's laboratory for future research related to cancer.

Before your blood samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical. Your samples will be given a code number. No identifying information will be directly linked to your samples.

Optional Procedure #2: If you agree, tumor tissue leftover from your standard of care surgery will be collected and used to learn if exercise has any effect on your immune system and the structure of the tumor and surrounding tissue. After that testing is complete, any extra tumor tissue leftover will be stored in a research bank at MD

Anderson for use in future research related to cancer.

Before your tumor samples can be used for research, the researchers must get approval from the IRB of MD Anderson. Your samples will be given a code number. No identifying information will be directly linked to your samples.

Optional Procedure #3: If you agree, you will complete questionnaires about your quality of life and physical activity about 3-6 months after surgery. They should take about 15 minutes to complete.

There are no benefits to you for taking part in the optional procedures. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

MD Anderson and others can learn about cancer and other diseases from your **banked samples.** In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy. Sometimes your samples may be used for genetic research. The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

If you withdraw your consent to the storage of leftover blood or tissue samples for research purposes, then they will no longer be collected for storage. Any of your samples that remain stored will no longer be used for research and will be destroyed. However, if any of your samples were already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy them.

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.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have additional blood drawn for research testing related to inflammation and other exercise-related blood markers and to have any leftover blood from those samples stored for future research related to cancer?

YES **NO**

Optional Procedure #2: Do you agree to allow leftover tumor tissue from your surgery to be used for research purposes and to be stored at MD Anderson for future research?

YES **NO**

Optional Procedure #3: Do you agree to complete questionnaires about your physical health and quality of life about 3-6 months after surgery?

YES **NO**

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 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.

The funding for the resistance tools will be provided from the personal research funds (composed from philanthropic donations) of the study doctor, Dr. Katz. The resistance tools in this study will be provided at no cost to you.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

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, but you will be allowed to keep the resistance tubes/bands after you complete this study.

Additional Information

4. You may ask the study chair (Dr. Matthew Katz, at 713-792-6940) 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 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.

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/or shared with other researchers and/or institutions for use in future research.

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.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

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
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

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
(Adult Participants Only)

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

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2020-0026.

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

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
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

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____Other parent is deceased, unknown, incompetent, or not reasonably available.

____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

____The IRB has determined that the signature of both parents is NOT required.

WITNESS TO PARENTAL/GUARDIAN PERMISSION

I was present during the explanation of the research to be performed under Protocol 2020-0026. The child participant was also present. In my opinion, the parent(s)/guardian provided permission for the child to participate in the research.

_____ _____
SIGNATURE OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other: _

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

_____
PRINTED NAME OF MINOR

WITNESS TO ASSENT

I was present during the explanation of the research to be performed under Protocol 2020-0026. The child participant was also present. In my opinion, the child assented to participate in the research. (Note: If obtaining assent, a witness signature is required.)

_____ _____
SIGNATURE OF WITNESS TO THE ASSENT (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE ASSENT

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 below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION