IRB USE ONLY
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Name of Funding Agency (if applicable):

Consent for Participation in Research

Title: Application of ergogenic aids to the prehabilitation of abdominal cancer patients undergoing surgery

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

The purpose of the proposed pilot study is to determine the impact of a prehabilitation program by incorporating exercise and nutritional aids utilized by athletes, in patients who previously have abdominal cancer and will undergo surgery.

A description of this study 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.

What will you be asked to do?

If you agree to participate in this study you will complete a 4-6 week home based blood flow restriction exercise training and nutrition intervention. After you receive a health evaluation performed by Dr. Declan Fleming or Dr. Kimberly Brown, you will visit the Cardiovascular Aging Research Laboratory on 5 separate occasions (~2 hours per visit).

Session 1-- You will
1. complete 5 questionnaires related to your general health status and lifestyle
2. have your height, weight and arm & thigh circumferences measured;
3. perform a timed up and go test; which you will stand up from a chair, walk 3 meters (10 feet) away, turn and walk back to the chair and sit down;
4. perform a hand grip dynamometry test in which you squeeze a measurement device as hard as you can for a few seconds;
5. complete a personal training session to prepare and educate you on the exercise and nutrition program that will be implemented over the following weeks.
6. complete SPPB (Short Physical Performance Battery Assessing Lower Extremity Function). You will perform a series of short balance and mobility test to objectively assess frailty.

7. complete a 10-minute walk on treadmill while wearing blood flow restriction cuffs. Your blood pressure and heart rate will be measured continuously throughout the session.

Sometime after your appointment with Dr. Fleming or Dr. Brown and prior to Session 1 a member of the research team will call you or sit down with you to collect information on your nutrition and dietary habits.

Session 2—You will
1. Arrive after an 8 hour fast and a blood sample will be drawn by a certified phlebotomist. The blood sample will be used to quantify physiological and biochemical changes due to the 4 week prehabilitation training program.
2. complete a walking test in which you walk as far as you can in 6 minutes.
3. complete a personal training session. During the personal training session, you will be supervised as you demonstrate your ability to successfully complete the exercise regimen that was introduced to you and that you practiced during Session1.

4. **Optional Testing During Session 2-** You will
Have the option to have additional testing of your vascular function and body composition. These tests are a supplement to or an addition to the primary study. You can choose not to do them and still do the study. If you choose to opt in for the additional testing procedures, prior to the second visit, you must fast for a minimum of 4 hours and abstain from alcohol and caffeine for the previous 12 hours and from strenuous physical activity for the previous 24 hours.

1. Vascular function will be assessed by inflating a cuff that is placed on the arm to block blood flow to the hand for 5 minutes. During these tests, a fingertip temperature sensor will be placed on the skin of your fingertip. Your body's response to the stress will be measured (by the temperature sensor placed on the fingertips) before and after the cuff is released.
2. DXA (dual energy X-ray absorptiometry) will be used to assess body composition. You will lie on a padded table while a small probe that emits energy to measure tissue density passes over your body. This test does involve a small amount of radiation (less than 10% and 20% of a normal X-ray for those under and over ~215 lbs, respectively). Females taking this test and signing this consent form are acknowledging that to the best of their knowledge, they are not pregnant. Females will also be asked if they are pregnant (in the Health and Fitness Screening Questionnaire and verbally by our technician). Those answering yes or unknown will not be allowed to participate in this procedure.

Session 3—will be completed during the 3rd week of the exercise and nutrition intervention. You will return to the Cardiovascular Aging Research Laboratory to receive a personal training session to prepare and educate you on the exercise training protocol that will be implemented over the following 2 weeks.

Session 4 —you will be supervised as you demonstrate your ability to complete the newly assigned physical exercise for successful performance of the prescribed intervention for the following 2 weeks.

Session 5— after completion of the 4-6 week intervention, post testing will take place at the Cardiovascular Aging Research Laboratory. Baseline measurements from sessions 1 and sessions 2 will be repeated after 4 weeks of training. Additionally, an overall program satisfaction questionnaire will be administered.

After Training Intervention

- You will undergo routine pre-surgical care (Enhanced Recovery After Surgery Protocol, ERAS) prescribed by either Dr. Fleming or Dr. Brown the week prior to your scheduled surgery.
- **Immediately Post Surgery:** You will be give an accelerometer/ pedometer which will monitor your physical activity
- **30 days Post Surgery:** You will once again visit the Cardiovascular Aging Research Laboratory to have the Hand Grip Dynamometry and Timed Up and Go test administered to measure physical performance along with 2 questionnaires which inquiry about your quality of life and balance.
- **90 days Post Surgery:** You will be administered 2 questionnaires which inquiry about your quality of life and balance. Your medical records will be accessed by our research personnel team to evaluate any complications and readmissions to the emergency room you may have had.

All training assessments will take place either in the research laboratory (Bellmont Hall Rm 842A) or the Fitness Institute of Texas (Bellmont Hall Rm 966). This study will take a total of ~ 6 weeks to complete and will include approximately 100 study participants.

Exercise and Nutrition Intervention:

- You will be provided with all necessary equipment to implement the exercise routine in the comfort of your home.
- You will be asked to exercise at least 6 days a week. Three days a week (every other day) you will be asked to perform body, leg and arm exercises against light resistance (tubes or bands) while wearing arm and leg bands that restrict blood flow. Each exercise will take about 1 minute and the entire exercise session will last approximately 45 minutes. On the alternate days you will walk for approximately 15 minutes while wearing the bands that restrict blood flow. You will be taught how to do the exercises during Sessions 1 and 2 and you will be given access to a web site that has a video of the exercises for you to follow. After each exercise session you will provide feedback to the investigators on how you thought the session went (how difficult the session was, did you complete all of the exercises, etc.) by phone, text or e-mail.
- You will consume the provided nutrition supplement cocktail within 1 hour after completing each exercise session. The 4 Week Nutrition (Sports Drink) Supplement Cocktail: will include whey protein (25 g/day), creatine monohydrate (8 g/day), and L-citrulline (5 g/day). The supplement mixture will be provided in daily packages by the investigators.
- Throughout the intervention period, we will implement constant support or contact through telephone calls, texts, online feedback, etc. to attend to any concerns, to both provide and receive feedback and motivate you.
- Spousal Survey: A survey which inquires about your exercise habits and routines will be administered to your spouse, caretaker, and/or close relative as a means to measure your adherence to the exercise program.

- Additionally, an Exercise Diary will be given to you to fill out for every exercise session you complete.

NOTE:
This is a research study and, therefore, not intended to provide a medical or therapeutic diagnosis or treatment. The intervention provided in the course of this study is not necessarily equivalent to the standard method of prevention, diagnosis, or treatment of a health condition.

What are the risks involved in this study?

The procedures used in this investigation pose minimal risk to our participants. Nevertheless, risks associated with the vascular function testing may include temporary discomfort (numbness and/or tingling) at the fingertips during and after cuff inflation; symptoms usually subside within 30 seconds following cuff deflation. Other risks may include fatigue, cramping, slight increases in blood pressure, and shortness of breath and/or dizziness. Digestive discomfort can possibly be associated with increased nutrition supplementation. Possible risks associated with the sports drink you will be consuming include; digestive discomfort, nausea, and/or diarrhea. However, these risks can be reduced and or prevented by drinking adequate amounts of water (11-15 cups; recommended by the National Academy of Medicine) and maintaining a normal diet. Additionally, you may stop using the nutrition cocktail if you feel too sick to continue.

In addition, potential musculoskeletal injury (i.e., sprains, strains, and falls) can occur during performance testing or exercise performance. Delayed onset of muscle soreness is also possible. Blood draw risks are associated with soreness and bruising at the site of the blood draw. This risk will be mitigated but using good clinical practice, and providing professional supervision, consistent communication and regular monitoring throughout the duration of the study.

What are the possible benefits of this study?

Although potential benefits cannot be guaranteed from participation, they may include: increase in strength, physical performance, muscle size, improved recovery and reduced perioperative complications (if our hypotheses are supported by the results).

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with The University of Texas at Austin (University), your doctors, or Dell Medical School.

If you would like to participate, please sign this informed consent form and return it to the investigator. You will receive a copy of this form.

Will there be any compensation?

No monetary compensation will be provided for participation in this study.

What if you are injured because of the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin. However, you are not waiving any of your legal rights by participating in this study.

How will your privacy and confidentiality be protected if you participate in this research study?

Any information that is obtained in this study and that can be identified with you will remain confidential and will be released only with your permission. Your responses will not be linked to your name in any written or verbal report of this research project. The researchers might use information learned from this study in scientific journal articles or in presentations. None of this information will identify you personally.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact the researcher Hirofumi Tanaka at 512-232-4801 or send an email to htanaka@austin.utexas.edu for any questions or if you feel that you have been harmed.

This study has been reviewed and approved by The University Institutional Review Board, Study Number: 2018080110

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu. Study Number: 2018080110

Participation

If you agree to participate, please sign below.

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ Please initial if you want to opt IN and have the optional vascular function testing. One of the investigators for this study, Dr. Hirofumi Tanaka, is an unpaid member of the Endothelix Scientific Advisory Board. Endothelix manufactures the Vendys II device used for vascular function testing in this study.

_____ Please initial if you want to opt IN and have the optional DXA body composition testing.

_____
Printed Name

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____
Print Name of Person obtaining consent

_____ _____
Signature of Person obtaining consent Date