INFORMATION LETTER TO PARTICIPANTS

Project Title

Supervised versus home-based exercise prior to surgery for prostate cancer patients scheduled for prostatectomy.

Purpose

Prostatectomy, the main treatment for localised disease, is associated with adverse effects. This impact is particularly damaging given the potentially low physical reserve capacity of prostate cancer patients. Traditionally, exercise medicine interventions have focused on post-surgical recovery. However, an opportune time for exercise medicine is pre-surgery to negate the treatment-related adverse effects thereby aiding recovery, and enhancing patient outcomes. This study will evaluate an exercise medicine intervention undertaken pre-surgery aimed at enhancing pre-surgical physical function, quality of life and improved post-surgical recovery.

Procedures

Participants Involvement

We require men who are recently diagnosed with localised prostate cancer and are scheduled for prostate surgery to participate in this research study. To be eligible, participants must:

1. Localised prostate cancer.
2. Have at least seven weeks between diagnosis of cancer and surgery date.
3. No acute illness, musculoskeletal, cardiovascular or neurological disorder that could place the participant at risk of injury or illness resulting from the exercise. (This will be determined by your doctor (GP) who is required to provide their consent and clearance to exercise. It is essential to note that you may need to make an appointment with your GP and there may be an out-of-pocket cost).
4. Ability to walk 400m unassisted and undertake upper- and lower-body exercise.
5. Not be performing regular exercise defined as undertaking structured aerobic or resistance training two or more times per week within the past 3 months.
6. Be able to read and speak English.

If you choose to participate, you will be randomly assigned (i.e. by chance) into one of two groups: 1) supervised exercise group; 2) home-based exercise group. Both groups will immediately commence a 6 weeks' exercise program till prostate surgery. The supervised group exercise would be prescribed and monitored by exercise physiologists. The home-based exercise group will be provided with an exercise information booklet and information on a 6-week home-based exercise program with weekly telephone calls.

Participants will be screened for study eligibility by an exercise physiologist with expertise in cancer rehabilitation. Participants will then be asked to complete a number of questionnaires which ask detailed questions about their health, physical condition and wellbeing as well as the level of anxiety they are experiencing if any. If you choose to participate you may experience some discomfort answering the items in these questionnaires. However, all responses will be kept strictly confidential.

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Exercise Program

The exercise program involves resistance (e.g. lifting weights) and aerobic (e.g. walking, cycling) exercises performed 3 times per week for 6 weeks in an exercise clinic. The sessions may be conducted in small groups of up to 10 participants supervised by accredited exercise physiologists. Sessions will take approximately 60 minutes and will be conducted across various sites in Perth, WA. The resistance exercise component will involve 6-8 exercises that target the major upper and lower body muscle groups. Intensity will be manipulated from 6-12 repetition maximum (RM; i.e. the maximal weight that can be lifted 6 to 12 times) using 2-4 sets per exercise. To ensure the progressive nature of the training program, participants will be encouraged to work past the specific RM prescribed. The exercise program will be progressive and modified according to individual response. This will be followed by 15 minutes of exercises focusing on the trunk stabilising muscles which include 3 sets of 3 different exercises [planks (anterior abdominals), reverse bridge on Swiss ball (back extensors) and side planks (oblique abdominals)] with a rest of 30 to 60 seconds between sets. These will start at 15-30 sec and progress gradually to at least a 1 min per set. The aerobic exercise component will include 20 to 30 minutes of moderate to vigorous intensity cardiovascular exercise using a variety of modes such as walking or jogging on a treadmill, cycling or rowing on a stationary ergometer or exercising on an elliptical or cross trainer machine. Participants in the exercise program will be encouraged to undertake additional home-based aerobic exercise with the goal of achieving a total of at least 150 minutes of moderate intensity aerobic exercise each week.

Home-based exercise group

You will receive an exercise information booklet and will be requested to complete at least 150 minutes of aerobic exercise per week in sessions of 20 minutes or more and 2-4 sets of 10-12 repetitions of body weight resistance exercises (push-ups, chair dips) and exercises using a gym stick (biceps, squats, leg extension, calf raises, seated-rows) at least three times per week. The exercise physiologist will be conducting weekly telephone calls, during which time clients can discuss their exercise activity and any study related questions. The exercise booklet contains generic information about physical activity, health benefits of exercise, methods of measuring exercise intensity, and a logbook section. Only the initial exercise session will be conducted by the accredited exercise physiologist to demonstrate exercises. Information on performing exercises on the trunk stabilising muscles similar to the exercise intervention will be provided.

Assessments

All participants in this research study will be required to complete a series of assessments that will occur at 0 months (start of intervention), pre-surgery, 6 weeks' post-surgery and a 24-hr urinary pad test at 12 weeks' post-surgery **(end of intervention)**. The expected study time would approximately be around 4-5 months. Additionally, a 24-hr urinary pad test will also be undertaken after discharge from the hospital. These will be completed at Edith Cowan University Joondalup Campus.

- **Physical Function**
    - A series of standard tests will be used to assess physical functional performance. Before the tests are performed demonstrations, practice time, sufficient warm-up will be undertaken and participants will be supervised by qualified professionals. These tests involve:
    - 400 metres corridor walk: Participants will be asked to walk 20 meters in a corridor, turn and return to the starting position and repeat another 9 times as fast as possible.
    - One repetition maximum test: Maximal muscle strength will be determined for three of the resistance exercises performed during the exercise training sessions using

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weight-training machines (leg press, chest press and seated row). The maximal strength is the most weight that can be lifted one-time using correct technique.
    - Muscle endurance test: The maximal number of repetitions performed on chest press will be measured. Muscle endurance scores for pre- and post-surgery assessments will be determined using the baseline load.
    - Repeated chair rise: Participants will be seated in a chair and asked to rise and sit 5 consecutive times, without the use of their arms for support, as fast as possible (performed 3 times).
    - 6 metres walk: You will be asked to walk 6 metres at your usual pace and at a fast pace (i.e. as if you were running late for an appointment) (performed 3 times).
    - 6 metres backwards walk: As a test of balance, participants will place one foot will behind the other and will be asked to walk backwards 6 metres (performed 3 times).
    - Stair climb: You will be asked to ascend a flight of stairs (11 stairs) as fast as possible.
- **Body Composition**
    - Dual Energy X-Ray Absorptiometry (DXA) will be used to assess whole body composition (fat mass and lean mass). This assessment involves lying still on a specifically designed platform for approximately 5 minutes and a scanning arm will move above your total body. A low-dosage x-ray will pass from underneath the platform to the scanning arm. The total radiation dose for all scans undertaken during the study is very low, only a little more than normal background radiation from an airplane flight and much less than, for example, an international flight. The test is conducted by the chief investigator at the university and there will be no cost involved.
- **Incontinence**
    - A 24-hour pad test where grams of urine loss will be measured in a 24-hour period is conducted at 3-time points after the surgery (immediately after discharge date, 6 and 12-week post-surgery). Pre-weight absorbent pads will be given to you and 24-hours later used pads will be collected and weighed.
- **Questionnaires**
    - Participants will be asked to complete standardised questionnaires used to record demographic and health history information as well as to assess sexual health (including erectile function, sexual desire and overall satisfaction), sexual self-confidence, masculine self-esteem, quality of life, urinary bowel and hormonal issues, psychological anxiety, depression and anxiety levels, fatigue, body image and usual leisure time physical activity habits. This questionnaire will be completed at all assessments time-points and will take approximately 1 hour to complete (these can be done at your own time at home).

If you agree to participate in this study, you will be asked to provide consent to researchers having access to your medical records. We may require access to your medical records through your general practitioner so that we can get important information required for the study. This includes details of your cancer diagnosis, cancer treatment, relevant comorbid conditions, length of hospital stay data, as well as medications you are taking.

Risks

Any exercise may result in mild discomfort and muscle soreness. Furthermore, there is the possibility of muscle pulls or strains associated the exercise, common to any type of physical activity. In order to minimise these risks participants will perform an adequate warm-up and cool-down before and after any exercise bout, be comprehensively instructed on the correct lifting technique, thoroughly

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familiarised with the movements involved in this investigation and supervised at all times by qualified professionals. Risk of falling may exist in the performance of some tasks, however, participants will be closely supervised and spotted to prevent a fall from occurring. Furthermore, during exercise, it is possible to experience symptoms such as abnormal blood pressure, fainting, light-headedness, muscle cramps or strain, nausea, and in very rare cases heart rhythm disturbances or heart attack. These potential risks are common to any form of physical activity.
All home-based patient will be given recording sheets and instructions on the amount, type, intensity and volume of safe exercise limits. Record of the activity will be taken and investigators will follow up with a weekly telephone call. Home-based patient will be provided with a session educating them on the exercises that they will be doing at home.Some of these exercises consist of using their body weight as a resistance and other will be using a device called a Gymstick, which is essential, a pole with elastic strips. This device would also come with a DVD and tutorial manual. In the event that an emergency occurs, medical assistance will be obtained from the University Health Service according to our established emergency procedures by calling the Campus security on 63043333 or dialling 000. Each exercise physiologist is also first aid and CPR trained.
DXA scans are routine clinical tests but carry a small risk to the patient. DXA involves exposure to radiation. The level of radiation exposure is exceedingly small (10-30 microSieverts [µSv]) in comparison to the natural annual radiation dose in western communities (approximately 3000 µSv). A person would receive radiation exposure of approximately 80 µSv on an airline flight of 8 hours or 30 to 40 µSv during a typical chest x-ray. The number of scans proposed in this study is well within the guidelines provided by the manufacturer of the DXA machines.
Surveys and questionnaires are a routine part of clinical tests and data collection. There is a possibility that some questions on sensitive topics such as sexual health and incontinence may be very uncomfortable to answer. In order to minimise this discomfort and to keep the confidentiality, your de-identified questionnaire will be handled (data recorded) by a third party who would have no connection to the research study and your identity will not be revealed. For others, these questions may bring about an emotional or psychological response that may cause some anxiety or discomfort. In order to minimise this risk, participants are urged to contact the research investigator or the sexual health and incontinence nurse from the hospital for support. As a participant, you should contact a member of the research team if you are concerned about the potential of any adverse effects or if you experience any adverse effects following any of the tests and/or the exercise sessions.

Benefits

The significant benefits of exercising have the potential to improve participants' health outcomes, improving strength and fitness, reducing fatigue levels and potentially increasing cancer survivability. Besides the immediate benefits to the participants, this exercise program can lead to altering future prostate cancer patient management. Overall, this research is a critical step in a series of studies required to determine the most effective and efficient ways to maximise prostate cancer patients' health and therefore lay the foundation for future research. Moreover, all study activities, including the exercise instruction and training as well as all assessments, are provided at no cost to the participants.

Confidentiality

Your results will be kept confidential with all data kept in the possession of the investigators. If the results of the study are published in a scientific journal, your identity will not be revealed. Participants will not be referred to by name during research reports or study discussions. All records will be stored in a locked filing cabinet with restricted access for a minimum of ten years in a private document

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storage room in the exercise medicine research institute. All data will be destroyed after 10 years. DXA scan data will be destroyed after 50 years. All computer records are restricted by password.

Feedback

All participants will be provided with test results as soon as they are available. A summary of study results will be made available to all interested participants upon completion of the trial.

Voluntary Participation

Whether you decide to participate in the study or not, your decision will not prejudice you in any way. No explanation or justification is needed if you choose not to participate. If you do decide to participate, you are free to withdraw your consent and discontinue your involvement at any time.

Withdrawing Consent to Participate

Participants are free to withdraw their consent to further involvement in the research project at any time. If you decide to withdraw after initial baseline assessment, then your data may still be useful to us and assist with our study. If you wish to withdraw all information from the study, then you may do so by indicating this to us in writing.

Privacy statement

The conduct of this research involves the collection, access and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes. However, your anonymity will at all times be safeguarded. Further research with this anonymous data will be subject to further Ethics approval(s).

This project has been approved by the ECU Human Research Ethics Committee.

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Contacting the Investigators

We are happy to answer any questions you may have at this time. If you have any queries later, please do not hesitate to contact either:

Dr Favil Singh Phone: (08) 6304 2369 Email: f.singh@ecu.edu.au
Prof Daniel Galvão Email: d.galvao@ecu.edu.au
Prof Rob Newton Email: r.newton@ecu.edu.au

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Edith Cowan University Human Research Ethics Officer
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au