Participant Information Form

Project title	*Cognitive impairment in survivors of prostate cancer: combining cognitive and physical activity for a brain fog fix*
Study contact details	Email: prostatebrainhealth@canberra.edu.au Phone number: **0405 645 139**
Clinical Trial Registration	This research project has been registered with the Australia and New Zealand Clinical Trial Registry: **ACTRN12623000767606.**
Chief Investigator	**Professor Ben Rattray** University of Canberra Phone: 6201 5145 Email: ben.rattray@canberra.edu.au
Research Team	**University of Canberra** Dr Joe Northey, Mrs Alanah Pike, Professor Catherine Paterson and Dr Kristy Martin **Australian National University** Professor Nicolas Cherbuin, Dr Ganes Pranavan (Medical Oncologist) **University of Melbourne** Dr Amit Lampit **ACT Prostate Cancer Support Group** Mr Greg McRoberts

1. Introduction

The University of Canberra Research Institute for Sport and Exercise and Active Brain Research Group invites you to take part in the above project conducted by Professor Ben Rattray.

This participant information form is designed to inform you about the research project and your role and rights as a participant in the study. Please read this statement carefully and ask questions about anything that you do not understand or want to know more about.

If, after considering the information provided in this document, you wish to be a participant, you will be asked to read and sign a participant consent form. By doing so you are confirming that you:

- Understand the information you have been provided in this document
- Are fully aware of the procedures and risks involved in participation in the study
- Give consent to the use of data collected as described in this document

You will be given a copy of this participant information statement to keep.

2. What is the purpose of this project?

A common and debilitating side-effect of prostate cancer and its treatments are declines in brain health. Despite known cognitive changes amongst clinicians, patients, and their close supports, there is little research into the impact of potentially protective behaviours like physical activity in prostate cancer. The project will compare four different 8-week training interventions. Participants will be randomly allocated to one of the interventions being either:

1. Physical-only training involving 1 hour of moderate-intensity cycling twice per week;
2. Cognitive-only training involving 1 hour of training using a computerised cognitive tool twice per week in a seated, relaxed environment;
3. Concurrent physical and cognitive training involving 1 hour of cognitive training whilst cycling at a moderate intensity twice per week;
4. or a wait-list control where participants will maintain their usual care before being offered to participate in one of the training interventions.

Assessments before and after the intervention involve cardiovascular fitness, various cognitive function tests and a blood test. As compensation for your time and parking expenses, **you will receive a $360 VISA gift card after the study.**

The outcomes of this study will provide much-needed information on the experiences of men affected by prostate cancer, to provide targeted supportive care interventions to optimise brain health and well-being.

3. Who can participate in this project?

The project aims to recruit male participants aged 18 years or older, diagnosed with prostate cancer and currently receiving primary Androgen Deprivation Therapy (ADT) (inclusive of new anti-androgens) for either metastatic or nonmetastatic hormone-sensitive prostate cancer.

Additional inclusion criteria for all participants includes:

- undertaken **at least once dose of** ADT in the last 6 months
- have not received chemotherapy or radiation within the last 3 months
- not currently receiving steroids equivalent to more than 10 mg of prednisolone a day
- no opioid-based medication within the last 28 days
- self-assessed English proficiency
- absence of self-reported major psychological illness (e.g. psychosis or bipolar disorder) or neurological disease (e.g. stroke, Parkinson's disease, dementia)
- no history of central nervous system cancers
- ability to complete the cognitive function assessment (e.g. not colour-blind)
- ability to complete exercise bout on a recumbent bike and
- life expectancy of >12 months

4. What am I required to do as a participant in this project?

If you are interested in participating in this study, we will first arrange a preliminary conversation over the telephone to confirm your eligibility and answer any questions you have.

Once your eligibility is confirmed, you will be asked to:

- perform assessments before and after the 8-week intervention. These will include attending a Capital Pathology Clinic to have a blood sample collected (see 4.1 below), completing questionnaires (see 4.2 below) and attending the Faculty of Health Research Laboratory at the University of Canberra on two separate occasions (see 4.3 below). The total time commitment for the assessments in this project is ~5 hours.
- Undergo an 8-week training intervention which will involve attending the University of Canberra for one hour, twice per week (~16 hours of training in total – see 4.4 below).

4.1 – Blood draw (30 mins)

You will be provided with a referral to attend a commercial pathology provider within the ACT to have a fasted blood draw taken. We would ask that you avoid food and drink (except water) for 8-14 hours before your appointment (please let us know if you are diabetic). The pathology provider will collect around 20 mL of blood.

4.2 –Demographic and Health Surveys (30 minutes)

You will complete several short questionnaires which will ask you about your health, medications, and physical activity levels, as well as questionnaires related to the assessments and training. This will be completed in person either on paper or on a desktop.

4.3 – Lab Session 1: Cognitive and cardiovascular fitness assessments (1.5 hours)

In session 1, you will attend the Faculty of Health Research Laboratory at the University of Canberra to complete a short computerised cognitive assessment. During these tasks, you will sit at a computer screen with one of our researchers and work through a series of 5 tasks. Each test will be focused on a particular type of cognitive function including verbal memory, processing speed, visuomotor ability, executive function and working memory.

Following the cognitive assessment, you will complete an assessment of cardiovascular fitness on a recumbent stationary bicycle. An incremental test will be carried out whereby you will begin cycling at an easy level and additional resistance will be applied each minute. You will have an Electrocardiogram (ECG) which involves electrodes being placed on the chest connected by wires to a machine. This machine will monitor heart activity throughout the test and will be supervised by a clinician. This test will take approximately 5-10 minutes. Please wear comfortable loose-fitting clothing (e.g. shorts and a t-shirt) and enclosed shoes (e.g. joggers) for the exercise component.

4.4 – 8-week training intervention (~16 hours)

You will be randomly allocated into one of the four training interventions:

i. Physical-only training – 45 minutes of moderate-intensity cycling + 15 minutes of warm up/cool down on a recumbent stationary bike twice per week
ii. Cognitive-only training – 45 minutes of computerised cognitive training games twice per week
iii. Concurrent physical and cognitive training – 45 minutes of moderate-intensity cycling + 15 minutes of warm up/cool down on a recumbent stationary whilst completing computerised cognitive training games at the same time twice per week
iv. Wait-list control – you will maintain your usual routine for 8 weeks. After the post-intervention assessment, you will be invited to complete one of the training interventions above of your choosing.

5. What are the potential risks of participating in this project?

Participants consenting to participate in this project must be aware of the following associated risks:

1. Engagement in physical exercise incurs a small risk of injury or illness. To mitigate this risk, the research team will conduct the industry-standard Exercise and Sports Science Australia pre-exercise screening with each participant. This screening tool assesses an individual's expected risk when completing physical activity by asking a series of questions relating to their health history. During the short exercise assessment, you will be fully supervised and monitored by an Accredited Exercise Physiologist. Based on this assessment, the moderate-intensity exercise training prescribed will be supervised by exercise specialists, or Accredited Exercise Physiologist if deemed appropriate.

2. With the collection of blood samples, there is a small risk of infection, bleeding, clotting and fainting. The risks will be minimised as the samples will be taken by a trained technician under aseptic conditions and following best practice guidelines.

3. Some level of fatigue is expected as a result of the training interventions. This is common and required to allow for the intervention to work. The fatigue however should not be chronic, nor at a severity that impedes your ability to perform normal daily tasks. Fatigue will be monitored at each session and if you are particularly concerned, please reach out to one of the research team members. The risk of excessive fatigue is also managed through the timetabling of training sessions to allow more than a day between sessions.

6. What precautions are taken in response to the COVID-19 pandemic?

All research projects at the University of Canberra Research Institute for Sport and Exercise are undertaking extra health and safety precautions to eliminate the risk of spreading COVID-19. Some of these measures require the research team to wear additional personal protective equipment when you attend the laboratory which may include gowns, face masks and face shields.

Under the guidance of Government recommendations, the following strategies have been implemented:

- Extra cleaning protocols, for example, ventilating the testing laboratory with HEPA filters
- Changing cleaning products
- When physical distancing is not possible, all researchers will be wearing appropriate personal protective equipment
- Participant health and contact data will be shared with ACT Health in the event of a positive COVID-19 test result for contact tracing purposes
- Before each testing session, each participant will be required to complete a COVID-19 Pre-screening questionnaire to ensure it is safe to commence testing

7. Can I withdraw from the study once I've started?

Participation in the research is completely voluntary and participants may, without any penalty, decline to take part or withdraw at any time without providing an explanation or refuse to answer a question. To withdraw, you can inform a member of the research team verbally either in person or over the phone or in writing.

There will be no implications on the type of treatment or care offered to you by any treating clinician.

8. What are the benefits of participating?

As compensation for your time and parking expenses, you will receive a $360 VISA gift card at the completion of the study. You also have a right to receive feedback about the study's overall results. If you choose to receive feedback about the study by ticking the appropriate box in the consent form, you will be notified when the research is completed and, if it has been published, where you can access the findings. A meeting to disseminate the findings amongst the participants will also be organised after the study.

9. Confidentiality and Respect Statement

We appreciate that by participating in this study, you are likely to disclose personal health information and perform tasks which will challenge you. During the study, the research team and support staff will ensure the information you provide us is documented in confidence and only accessible to the researchers.

The research outcomes may be presented at conferences and written up for publication. However, in all these publications, the privacy and confidentiality of participants will be protected. All reports and publications of the research will contain no information that can identify any individual and all information will be kept in the strictest confidence.

The information collected will be stored securely on a password-protected computer throughout the project and then stored at the University of Canberra for the required fifteen-year period, after which it will be destroyed according to university protocols.

We will actively endeavour to provide you with a supportive environment which is safe and respectful. In return, we ask that you contribute to the safety of the environment by showing behaviours and communicating with us and other participants in the study in a way which is respectful and reflective of the professional and clinical environment we work in.

10. Ethics Committee Clearance

The project has been approved by the Human Research Ethics Committee of the University of Canberra (HREC – 11955).

11. Queries and Concerns

Queries or concerns regarding the research can be directed to the research team. Their contact details are at the top of this form.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the University of Canberra's Research Ethics & Integrity Unit team via telephone at 02 6206 3916 or email humanethicscommittee@canberra.edu.au.

If you would like some guidance on the questions you could ask about your participation please refer to the Participants' Guide located at http://www.canberra.edu.au/ucresearch/attachments/pdf/a-m/Agreeing-to-participate-in-research.pdf

Participant Consent Form

Project Title: *Cognitive impairment in survivors of prostate cancer: combining cognitive and physical activity for a brain fog fix*

I, ……., hereby consent to participate in the research project: ***Cognitive impairment in survivors of prostate cancer: combining cognitive and physical activity for a brain fog fix (UC-HREC 11955)***.

I acknowledge that:

☐ I have read and understood the participant information sheet which explains in plain language the purpose, participant experience, possible risks, and my rights as a participant.

☐ I am not aware of any condition that would prevent my participation in the project as explained to me in the participant information sheet and by the research team.

☐ I understand that my participation in this research is completely voluntary and that I can withdraw at any stage without consequence.

☐ I have had the opportunity to ask questions about my participation in the research. All the questions I have asked, have been answered to my satisfaction. **There will be no implications on the type of treatment or care offered to you by any treating clinician if you choose not to participate in this project. Your clinician will not be advised if you participate in this study. Additionally, if your treating clinician is a member of the research team, they will only have access to de-identified data.**

☐ Having my de-identified results included in scientific reports/articles and presentations.

☐ I must notify staff immediately if I become diagnosed with COVID-19, have had contact with a known or suspected case of COVID-19, or develop any cold or flu-like symptoms (cough, shortness of breath, sore throat, fever), even if mild.

☐ I will act and communicate with the research team and other participants in the study in a way which maintains other's confidentiality and is respectful of their privacy and safety. I understand that inappropriate behaviour will not be tolerated and may result in my removal from the study.

	Name	**Signature**	**Date**
Participant			
Researcher			

☐ Please provide a summary of the research project findings to the email address below.
☐ I would like to be contacted regarding a public symposium in which the project results will be presented.
☐ I would like to be contacted regarding future research projects conducted by the research team.

Email address (or preferred contact details): _____