Participant Information Sheet

Supportive care needs in prostate cancer (SUPPRO) – Phase II

Lead: Prof David Baxter, Dr Erik Wibowo

Study Site: University of Otago

Contact phone number: 64 3470 4692

Ethics committee ref.: 2021 EXP 11241

You are invited to take part in a study on supportive care needs in prostate cancer. We obtained your contact information from the database Cancer Registry, Ministry of Health, New Zealand. We ensure your personal information will be stored and managed properly. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will need to read the Consent Form on the last page of this document, it will also appear at the start of the survey. You can download a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is eight pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

A decision to take part in this study is entirely voluntary and it is entirely your decision whether to take part or not. Any decision regarding your participation will be confidential between you and the research team. You are also free to withdraw from the study at any time without any repercussions to yourself.

What is the purpose of the study?

Prostate cancer is the most commonly diagnosed cancer in NZ men, with an estimated 4,000 new cases each year. Men with prostate cancer are likely to have needs during the diagnostic, treatment, follow-up, and palliative phases, including psychological, spiritual, informational, physical, and sexual needs. The mortality rate of Māori men is over 1.5 times that of non-Māori men they may therefore have culturally specific needs. One way to improve the poor health status and to address these needs for men with prostate cancer is to provide good supportive care.

As a second phase in developing evidence-based community-based programs to improve the wellbeing and quality of life (QoL) of men with prostate cancer, we aim to determine the experiences and unmet needs of supportive care in the NZ prostate cancer population. We also would like to know how supportive care providers could deliver the best quality, patient-centered care and address areas that need improvements.

HOW IS THE STUDY DESIGNED?

You will be invited to participate in the questionnaire survey. Online or paper questionnaires are chosen based on your preferences. We would like you to complete a survey which should take you about 15-20 minutes to complete. We would like to know about your unmet needs about prostate cancer supportive care, your health-related quality of life, and your experience of supportive care utilization. This will enable us to understand the potential factors that affect the unmet needs of men with prostate cancer and to indicate the key elements for developing future community-based programs to improve the wellbeing and quality of life of men with prostate cancer in the future. The follow-up reminders and replacement surveys will be sent after two weeks to non-respondents with an option that you can choose to decline to receive them. The survey feedbacks are used for the analysis of the project and will not be used for any other purpose.

WHO CAN TAKE PART IN THE STUDY?

Access to the databases of men with prostate cancer will be obtained from the Cancer Registry, Ministry of Health. You may be involved in our survey study if: 1) you have been diagnosed with a first instance or recurrence of prostate cancer in each of the three time-point bands between 2017-2021 including: those within a year; between one and three years, and beyond three years up to five years of diagnosis of a first instance or recurrence of prostate cancer. 2) you are able to communicate in English; 3) you are able to provide written, informed consent to participate.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

There are two ways to complete the questionnaire. Firstly, you can complete the questionnaire online by receiving our survey invitation postcard (online survey link included). Secondly, you can request the paper questionnaire by contacting us and then return the completed questionnaire in the Freepost addressed envelopes that we have supplied. This can be posted directly to the Department of Anatomy, University of Otago, [Freepost ID/address], 270 Great King Street.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are no foreseeable major risks associated with study participation.
The sensitive questions may cause minor uncomfortable. We have added reminder signs before each sensitive question. So, you can also choose to skip these questions.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are unlikely to be direct personal benefits to you from this study. We will feedback our findings to you and keep you regularly updated about the study: 1) we will upload the summary of the results of each phase of the study to our study webpage (press release); 2) our strong engagement with stakeholders (Prostate Cancer Foundation and Cancer Society) will support better dissemination of the research findings into an understandable lay perspective (regular support group meetings).

WILL ANY COSTS BE REIMBURSED?

Your participation will not incur any costs. If you request the paper questionnaire, we will provide freepost addressed envelopes for you to post it back. There will be no reimbursement to participate the survey.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the research team members from School of Physiotherapy and Department of Anatomy, University of Otago will record information about you and your study participation. This includes the results of the data analysis. Information about your hospital records and your general practitioner may also be collected if the data from Cancer Registry shows you have advanced diseases. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The research team members, your general practitioner, Centre for Health Outcomes Measures New Zealand (CHOMNZ) and Prostate Cancer Outcome Registry NZ (PCOR) the will have access to your identifiable information.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the research team. Instead, you will be identified by a code. Our team members will keep a list linking your code with your name, so that you can be identified by your coded data if needed. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

If you agree, your coded information may be used for the recruitment of a follow-up interview study. Apart from this, your information will not be used in any other research and will not be sent overseas.

Security and Storage of Your Information.

Your identifiable information is held at School of Physiotherapy, University of Otago during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the University. Coded study information will be kept by the University in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Data collection for this study is expected to be completed by Dec 2023. All information you give will be treated in the strictest confidence. All data will be handled in accordance with the Privacy Act 2020. Your surveys will be kept in a secure cabinet in the university. The information you give us in the survey will be entered into an anonymized database that will not contain any personal details about you. The survey record will be destroyed after we complete the data analysis, but we will keep the information collected in this study for 10 years in a locked cabinet in the School of Physiotherapy and on the University's secure electronic data storage system.

Information Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

Rights to Withdraw Your Information.

You are free to withdraw from the study at any time without any repercussions to yourself by informing the research team. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Databank / Registry.

As part of this study, we will extract your identifiable information from Cancer Registry, Ministry of Health, and then submit your information into the Prostate Cancer Outcome Registry to run a check of the data. This process is mandatory as we would like to match the data of these two databases and ensure the validity of the data.

Cancer Registry NZ is a population-based tumor registry whose primary function is to collect and store cancer incidence data. Cancer incidence is defined as the occurrence of new cancers in a defined population in a specified time period. Cancer Registry NZ provides data for cancer incidence and survival studies, public health research, monitoring screening programs and policy formulation. Prostate Cancer Outcome Registry NZ is a large-scale prostate cancer registry that collects information on the care provided and the outcomes for men diagnosed with prostate cancer in Australia and New Zealand.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You will get reports or other information about any / some research that is done using your information. After the study has been completed, the major findings will be presented at national and international conferences and will also be submitted to an academic journal as a research article. It will also be presented on our centre and study webpage:

https://www.otago.ac.nz/mens-health/index.html.

If you wish, we will also inform you of the study findings by email.

WHO IS FUNDING THE STUDY?

This study is funded by Department of Anatomy Strategic Research Grant, University of Otago

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name, position: Hui Xiao, Postdoctoral Fellow
Telephone number: 022 108 9198
Email: hui.xiao@otago.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Maori health support please contact:

Name, position: Tobias Hoeta, Assistant Research Fellow

Telephone: number 64 278612501
Email: tobiashoeta@gmail.com

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Consent Form

Supportive care needs in prostate cancer (SUPPRO) – Phase II

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
I know that there is no cost and payment offered for this study
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
I am happy that all my questions about the project have been answered, and I understand that I am free to ask for more information at any stage.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.	
I know who to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I wish to receive a summary of the results from the study.	Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____