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Characterising prostate cancer patients undergoing hormone therapy: Is there a group of men more at risk of cognitive changes? A Cross-sectional Study

Information for Participants

You are invited to take part in this research study because you either:

- have been treated for prostate cancer.
- do not have prostate cancer.

Research studies include only participants who choose to take part. Before deciding whether or not to take part in this study, it is important that you read and understand the information below. It tells you why we are doing the study, what is involved in it, and any benefits or risks associated with taking part. It also describes your right not to participate or stop taking part in the study at any time. Please ask a member of the study staff to explain anything you do not understand. Make sure all your questions have been answered to your satisfaction before you decide whether or not to participate. Please take your time to make your decision. You can discuss it with your friends and family.

Purpose
The purpose of this study is to learn more about men's experiences with hormone therapy and their cognitive functioning. The results of this study will help us to develop better information resources and tools to support men making decisions about treatment for prostate cancer and those who are undergoing hormone therapy.

Who is conducting the study?
The study is being conducted by Lorna Huang (lorna.huang@hdr.mq.edu.au) to meet the requirements of a Doctor of Philosophy (PhD) degree under the primary supervision of Prof. Kerry Sherman (Kerry.Sherman@mq.edu.au) Deputy Head Department of Psychology. Other associate supervisors include: Dr. Heather Francis, Prof. Howard Gurney, Prof. David Gillatt and A/Prof. Haryana Dhillon. This research is endorsed by the Australian and New Zealand Urogenital Prostate Cancer Trials Group (ANZUP).

How many people will take part?
Around 150 people who, like you, have or have not been diagnosed with prostate cancer will take part in this study.

What is involved?
If you are interested in taking part in this study, you will be asked to consent to taking part by ticking the 'yes' box on the questionnaire. To be eligible for study participation you need to be:

- Over 17 years old;
- Able to read and speak English sufficiently well to respond to written questions;
- Able to provide consent;
- Fit one of three categories:

    i) diagnosed with prostate cancer, who are currently undergoing hormone therapy;
    ii) diagnosed with prostate cancer, who have are on 'watchful waiting' or 'active surveillance';
    iii) without a prostate cancer diagnosis.

When you have consented, you will fill out a form that asks some questions about:

- You and your life generally
- Diagnosis and treatment
- Health
- Cognition
- Mood
- Intellectual engagement

We will ask you to fill out the online or paper survey one time only. It will take you about 20-30 minutes to fill out the form.

If you and your partner are willing to talk about your experiences further, there is an opportunity to participate in an optional online or telephone interview. Continue reading for more information.

Information about your cancer treatment (if applicable)
You will need to provide some details about your prostate cancer and the treatment you had with your treatment team.

Optional Interview
If you are experiencing cognitive difficulties, we are particularly interested in speaking with you in more detail. We would also like to invite your partner to talk about his/her opinions about any cognitive changes seen in you due to prostate cancer. You and your partner will be compensated for your time with a gift voucher worth $100 AUD ($50 each).

If you and your partner are interested in taking part in the interview, you can provide your details (i.e., name, phone number, email address) in the survey. If you are not interested in participating in the interview, please do not provide your details.
A member of the research team may contact those who have provided their details and organise a time to conduct the interview. You have the opportunity to opt out at any time, if

you no longer want to participate. Not all participants who have provided their details will be contacted.

The interview will happen with a member of the research team. Your talk with them will be recorded. After the interview is over, the recording will be transcribed (written out exactly as it was recorded) to allow us to go over what was said in detail after. The discussion will be guided by some questions about your experience. The topics we will ask about will include:

- Any cognitive changes you have experienced;
- The types of cognitive changes;
- Impact of these changes on your life.

The interview can be done over the phone, and it will be at a time that suits you. It will take between 30 – 60 minutes of your time, one time only.

If you are interested in doing the interview now but change your mind later, you can let us know that you no longer want to take part when we call. Changing your mind will not affect your treatment, relationship with the medical team, or participation in other parts of the study.

How long will my involvement take?
Both the survey and the interview will take up no more than 1 to 1½ hours of your time in total. The survey being around 20-30 minutes and the optional interview being around 30 -60 minutes.

What will happen to information collected about me?
Information received from you will be accessed and stored by the researchers at Macquarie University. The information will be stored in the secure electronic study database at Macquarie university. The database is protected by passwords, so only people with approval can access it. Any paper surveys you fill out will be scanned and stored on the server, the paper copies will be destroyed by secure shredding. This information will be used to work out the study results.

It will not be possible for anyone to identify you by looking at the database that has your answers to the survey and health information . The information we collect about you will be stored using a code to identify you. Your name, address and contact details will not be stored with your information. The information collected will be kept for at least seven years; when the information is destroyed it will be done securely. The deidentified data collected from the study may be made publicly available in an online repository (as it is becoming a common practice when publishing in scientific journals).

Risks & Benefits
There are no known risks associated with the study. However, you may find the survey questions raise things you had not thought about before. Some people may find the questions upsetting. If this occurs, you can talk to a member of the research team to discuss your concerns . You may alternatively wish to talk to one of the people in your treatment team or your GP .

Taking part in this study will not change your treatment or follow-up with your treating doctor in any way. Taking part in the study may not be of direct benefit to you, but the knowledge gained from this study will help with understanding the best way to care for people with prostate cancer.

What are the costs?
Taking part in this study will not change any of the usual costs of your medical care. You will not be paid for taking part in online or paper survey. If you choose to participate in the online or telephone interview, you will be compensated for your time (see 'Optional Interview' section for more details).

What about confidentiality?
Any information or personal details gathered in the course of the study are confidential, except as required by law. Only project researchers will have access to the data. Identifying information will be kept securely. Identifying information will never be included in a publication of the research. There is no intention that the data will be made available for use in future Human Research Ethics Committee-approved projects.

What are your rights as a participant?
The decision to take part in this study is your own. You may choose not to take part or may leave the study at any time. Deciding not to take part or deciding to leave the study later will not affect your care or treatment.

You will be told about new information that may affect your health, welfare, or willingness to stay in this study.

Questions
If you would like to know more about the study at any stage, please feel free to contact Lorna Huang on lorna.huang@hdr.mq.edu.au

Ethics Approval
This study has been approved by the Macquarie University Human Research Ethics Committee.

What you are agreeing to?
By agreeing to participate in this study you are acknowledging that you have read and understood the information above and any questions you have asked have been answered to your satisfaction. You acknowledge that you are agreeing to participate in this research, knowing that you can withdraw from further participation in the research at any time without consequence. You acknowledge that you will able to download a copy of this form to keep. If you have any reservations or concerns about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics & Integrity (telephone: (02) 9850 7854; email: ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

This is an online study. You are under no obligation to participate and will not be given the study URL until you have signed up for the study. In order to sign up for the study, you must agree to the terms of participation noted in the information and consent form.. You are free to stop the survey at any stage.

What can I do if I would like to speak more about my feelings?

If you would like to receive emotional support or further discuss your experiences, Cancer Council Support Line (13 11 20) or Lifeline Counselling Service (phone number 13 11 14) can provide more help. These services are provided free of charge.

PARTICIPANT CONSENT FORM

I, ……..……. *[name]* have read and understood the Information for Participants on the above named research study.

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the health professionals involved.

I freely choose to participate in this study and understand that I can withdraw at any time.

I also understand that the research study is strictly confidential.

I hereby agree to participate in this research study.

O Yes O No

Email address to send this information to: _____
Email confirmation: _____

I agree to be contacted about the study interview:

O Yes O No

Contact number: _____

Email address: _____

My partner agrees to be contacted about the study interview:

O Yes O No

Contact number: _____

Email address: _____

Participant name:

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Participant signature:

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Date:

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