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Can delayed screening reduce overuse of the prostate cancer screening test?
Developing a new model of care

PARTICIPANT INFORMATION STATEMENT - GP

(1) What is this study about?

You are invited to take part in a research study aiming to co-design a new model of care – 'delayed screening + decision support' - for prostate cancer screening. This approach aims to disrupt current overuse of the PSA screening test by introducing a pause in which men consider their choice, by engaging in a process of informed decision making. The ideas generated from this study will be used to inform development of a final model to be tested in the clinic in our future research.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the study. Please read this sheet carefully and ask questions about anything that you don't understand or would like to know more about. Participation in this research study is voluntary.

By giving consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

This Participant Information Statement is for you to keep.

(2) Who is running the study?

The study is being carried out by researchers led by Dr Kristen Pickles, Sydney School of Public Health, at the University of Sydney. Other members of the research team are Prof Alexandra Barratt, Prof Kirsten McCaffery, A/Prof Rae Thomas, A/Prof Kevin McGeechan, Dr Jolyn Hersch, A/Prof David Smith, Prof John Brodersen, Prof Paul Glasziou, and Mr Ross Smith.

(3) What will the study involve for me?

The study will be conducted as a series of online focus groups (conducted via Zoom). Focus groups are used to gather people's opinions and attitudes about certain services or concepts before being launched or taken to development.

Two researchers will facilitate your focus group, where you will be presented with information about prostate cancer screening, decision aids, and healthcare intervention design and development, and introduced to the concept of delayed screening. You will be asked to contribute to the design of a new model of care incorporating the delayed screening method, by sharing your opinions, experiences, and suggestions for this approach.

We also aim to conduct follow-up one-to-one telephone interviews with interested GPs to further explore the issues raised in the focus groups and to understand individual views on two decision aids that will be introduced in the focus groups. You will be asked to express your interest in participating in a telephone interview on the Participant Consent Form. Researchers will contact you to answer any questions that you might have and to arrange a time for the interview.

You do not need to do any preparation before the focus group or interview.

Focus groups and interviews (should you choose to participate) will be audio recorded and transcribed (typed out). The recording and the transcript will be identified by an ID number, not by your name.

When analysis of the resulting data is complete, researchers will provide you with a summary of the findings if you request that on your consent form.

(4) How much of my time will the study take?

The study involves one focus group which will take about 60-90 minutes to complete. You may choose to participate in an additional one-to-one interview by telephone or on Zoom, which will take about 30 minutes to complete. This will be scheduled at a time separate to the focus group.

(5) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney. If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting us via phone on +61 (0)2 9351 2064 or email at kristen.pickles@sydney.edu.au

If you take part in the focus group, you are free to stop participating at any stage without having to give a reason, and to refuse to answer any questions. However it will not be possible to withdraw your individual comments from our records once the group has started. This is because individuals will not be identifiable in the recording of the group discussion, so it will not be possible for us to identify that it is you who is speaking on the recording. Recording will be stopped and any recorded data deleted should you choose to stop participating in a follow-up interview.

(6) Are there any risks or costs associated with being in the study?

This is a low-risk project. Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study. Your confidentiality and anonymity will be protected. Your consent form contains some identifying information and will be kept in a secure data store at the University of Sydney. However these consent forms will not be linked in any way to the data and it will not be possible to connect anything you said in the focus group to your identity. Digital audio files will be kept on password protected servers at all times.

If you experience any anxiety or distress during the focus group or interview you are not obligated to continue and can speak to study researchers, the Cancer Council helpline (13 11 20), or the Prostate Cancer Foundation of Australia (1800 220 099) for support. Please contact researchers via telephone on (02) 9351 7220 or via email kristen.pickles@sydney.edu.au if you require further information.

(7) Are there any benefits associated with being in the study?

We cannot guarantee that you will receive any direct or immediate benefits from being in the study. However, our experience in similar work has shown that many participants value the opportunity to contribute to and have a positive effect on the safe and sustainable provision of health care services.

(8) What will happen to information about me that is collected during the study?

All the information collected from you for the study will be treated confidentially. The focus groups and interviews will be digitally recorded. The digital audio file will only be accessible to a sole transcription

provider and the named investigators working on the project. It will be kept on a password-protected server. We have a confidentiality agreement with our transcribing service provider.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored securely and your identity/information will only be disclosed with your permission, except as required by law. Study findings may be published in academic publications and communicated in conference presentations, but you will not be identified in these publications.

(9) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(10) What if I would like further information about the study?

When you have read this information, Dr Kristen Pickles, Chief Investigator, will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Dr Kristen Pickles +61 2 9351 2064 or kristen.pickles@sydney.edu.au or Professor Alexandra Barratt, alexandra.barratt@sydney.edu.au.

(11) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one-page summary of the research results. You will receive this feedback after the study is finished.

(12) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney (Protocol No 2019/925). As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies. If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

Telephone: +61 2 8627 8176

Email: human.ethics@sydney.edu.au **Fax:** +61 2 8627 8177

This information sheet is for you to keep