

**WHAT OUTCOMES ARE IMPORTANT FOR MEN
WITH ADVANCED PROSTATE CANCER? AN
INTERVIEW STUDY**

**PARTICIPANT INFORMATION SHEET
FOR
INTERVIEWS**

1. Introduction

We would like to invite you to take part in a research study. This leaflet tells you why the research is being done and what it will involve. We hope you will find this information helpful.

2. What is the purpose of the study?

Prostate cancer is an important and growing health problem for the nations of Europe. Advanced prostate cancer can be treated in a number of different ways and it is currently unclear which treatment is the most effective. The purpose of this project is to develop a standardised set of outcomes for the treatment of advanced prostate cancer which are important to all healthcare professionals, researchers and men diagnosed with advanced prostate cancer in order to optimise decision-making (i.e. core outcomes).

To achieve this, we want to investigate 4 questions:

- 1) Which outcomes are currently reported in advanced prostate cancer research?
- 2) Which outcomes are most important to men who have been treated for advanced prostate cancer?
- 3) Which outcomes do men and clinicians agree are important?

4) Is it possible to collect data on these outcomes in a study of men undergoing advanced prostate cancer treatments?

3. Why have I been chosen?

We would like to use interviews to help us answer questions 2 and 4 above. You have been chosen because your experiences of being treated for prostate cancer makes your views on what the important outcomes from the perspective of men diagnosed with advanced prostate cancer very important.

4. Do I have to take part?

No. It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

5. What will happen to me if I take part?

If you decide to join the study you will be asked to:

1. Sign the consent form for the study
2. Spare approximately one hour in a 1:1 online interview with the researcher who will

discuss your prostate cancer journey and aspects which have been most important to you throughout your treatment.

6. What are the possible disadvantages of taking part?

This qualitative project aims to ask you about prostate cancer because this is something which affects you but it is not essential to share sensitive or personal information with the group or researchers. However, there may be particular details which you feel could be beneficial for us to know or help us make improvements in our approach to men with prostate cancer in the future and this insight would be welcomed.

It is important for you to realise that should at any point during the interview you may become uncomfortable, you have the right to ask the interviewer to stop the interview and seek to destroy the data collected on you so far.

No health and safety risks have been identified.

7. What are possible benefits of taking part?

By participating in this study, you will be helping the research team to understand issues from the perspectives of men who have been diagnosed with advanced prostate cancer and informing future research in advanced prostate cancer.

This research will not affect your current treatment.

8. What if something goes wrong?

We do not think that taking part in this study will have any risks for your health. Your health care will not be affected.

You may withdraw from the study at any time, without giving any reason and without your medical care or legal rights being affected.

If you have a concern about any aspect of this study, you can speak to the researchers at any time. They will do their best to answer your questions and resolve your concerns. Should you experience any feelings of distress, please contact your local healthcare team or EUROPA UOMO (<https://www.europa-uomo.org/>).

9. Will my taking part in this study be kept confidential?

Yes, all information which is collected about you during the course of the research will be kept strictly confidential. All data will be given an identification number and will not be labelled with your name or any other information that directly identifies you. The connection between the identification number and you will only be stored on a password-protected University computer as per University of Aberdeen's data protection policies. : The University

complies with GDPR and the Data Protection Act and all information will be treated with the strictest confidence.

The only people who will be able to hear the audio-recorded discussion will be the research team and an accredited transcriber. The notes, interview recording and transcript will be treated confidentially. These will be stored safely and will be destroyed 10 years after the end of the study.

University of Aberdeen is the sponsor for this study based in Aberdeen, United Kingdom.

10. What will happen to the results of the research study

We will use the notes and transcript of the interviews to summarise which outcomes that the participants have raised as important to them. We will then use these outcomes in conjunction with others we have found in published research to create a list of outcomes that are measured in advanced prostate cancer. This list will then be put to a wider group of men diagnosed with advanced prostate cancer and clinicians to try and focus the list to the outcomes which are the most important. This will be done via a series of meetings and questionnaires. We also hope to publish the results in medical journals so that others can read about and learn from them.

All people taking part in the study will be sent a summary of the findings if they wish to receive them. If you are interested in the outcome of this research and would like further information or updates, then please let us know.

11. Who is organising and funding the research?

This study is being conducted by the University of Aberdeen. It is funded through the PIONEER consortium (IMI2).

12. Contact for further information

If you have any questions about the study, you can contact the research team using the details below:

Dr Sheela Tripathee
Email: sheela.tripathee@abdn.ac.uk

Or

Dr Sara MacLennan
Email: s.maclennan@abdn.ac.uk

Thank you for reading this information leaflet.