

Being well and well-being in the context of prostate cancer and creating a new quality of life questionnaire by, and for, persons affected by prostate cancer: Participant Information

You are invited to take part in a research study on how persons affected by prostate cancer define being well and well-being. It is well established that doctors are taught how to use the best posture and tone of voice to communicate with patients and those close to them, but little attention is given to what they actually say. This research will help healthcare professionals to ask the right questions and so understand better just how a patient is feeling.

The principal investigator of this research was diagnosed with locally advanced, high-risk prostate cancer in 2012 and relapsed from January 2018. In 2019, he received treatment for a secondary tumour and is currently waiting to learn whether further treatment is needed. As a person with prostate cancer, he is concerned that the current quality of life questionnaire used for patients with prostate cancer does not ask the right questions and that it makes all sorts of assumptions about what it is like to have the disease. A new questionnaire is needed, but it needs to be designed and created with, and by, persons affected by prostate cancer. It needs to reflect just what concerns us, and it needs to ask the kind of questions patients and those close to them would like to be asked.

Currently, in the United Kingdom, around 47,500 men are diagnosed each year with prostate cancer and around 11,000 die from the disease. There are around 400,000 men living with or after prostate cancer and, on average, one man in eight will develop prostate cancer in the course of his lifetime. Add to these figures the family, friends and relatives of these men and it is clear that a very large number of people are affected in some way or another by the disease.

The first phase of the research consists of a short survey to be completed online. This asks a little about you, your experience of the disease and how it has been for you. The questionnaire is anonymous. The second phase is interviews or focus groups to further interrogate key themes emergent from phase one. If you opt to take part in this second phase, you will need to follow a link from the survey to leave your contact details. Your survey responses will be entirely separate from your contact details and cannot be matched.

As the questionnaire is anonymous, responses cannot be attributed to individuals and all raw data will be treated as confidential to within the limits defined by law. Before deciding on whether to take part, please take time to consider the following information. Your participation is entirely voluntary.

What is the study about?

The study is an attempt to:

1. Examine what the notions of being well and well-being mean in the context of prostate cancer;
2. Find out the questions that patients and those close to them would like to be asked;
3. Work with patients and those close to them to design and pilot a quality of life questionnaire derived from patients' experiences and concerns;
4. Use this work to develop materials to help healthcare professionals ask the right quality of life questions (as determined patients and those close to them)

The survey questionnaire is a mix of open and closed questions and should take less than ten minutes to complete. The interviews and focus groups will last around 30 minutes or so. The target group for this research consists of anyone affected by prostate cancer.

Who has reviewed this study?

The FEHW Research Ethics Committee at the University of Wolverhampton

Who is being asked to take part?

Persons affected by prostate cancer.

What will happen to me if I take part?

in phase 1, you are asked to complete this questionnaire, which is quite brief and should take no more than about 5-10 minutes to complete.

Participation is entirely voluntary. If, for any reason, you do not wish to take part, then do not complete the questionnaire. At the end of this questionnaire, there is an invitation to take part in a follow-up individual or group interview, whichever is more convenient for participants. This is phase 2.

The questionnaire will remain open until the end of June 2020. Participation is entirely voluntary and, should you decide to withdraw, all data identifiable to you will be deleted.

What will happen to the data and will my taking part be kept confidential?

Only the researchers will have access to the questionnaires which will be downloaded and held on a secure University server for a period not exceeding five years, after which the data will be deleted. The survey is anonymous, unless you give your details to take part in a follow-up focus group or interview. In all instances, confidentiality will be guaranteed to within the limits of the law. Your responses to the questionnaire will not be linked to you or to your participation in a focus group.

Demographic data will be coded by simple equation of data with numbers [e.g. the first age group on the list will become 1, the second 2 and so on]. Quantitative data will be coded following a simple equation such as: strongly agree = 5, agree = 4, neither agree nor disagree = 3; disagree = 2; strongly disagree = 1

Qualitative data will be subject to emergent themes analysis using the constant comparative method. In this way, themes will be identified, the incidence counted, metaphors noted, opinions divided between positive and negative and so on until quantifying data emerges with illustrative quotes. All quotes used will be anonymised.

If you have any concerns, you can contact the Principal Investigator:

Dr David Matheson, d.matheson@wlv.ac.uk

If your concerns are not addressed, you can contact the Dean of Research:

Professor Silke Machold, silke.machold@wlv.ac.uk

To contact the University of Wolverhampton's Data Protection Officer you can:

- Email via dataprotection@wlv.ac.uk
- Phone on 01902 32 1000
- Write to Data Protection, Offices of the Vice Chancellor, University of Wolverhampton, Wulfruna Street, Wolverhampton, WV1 1LY.