Quality of Life during Treatment for Prostate Cancer: an exploratory study of electronic data collection.

Participant Information Sheet

We would like to invite you to consider taking part in study relating to your experience of prostate cancer and your quality of life following treatment.

This information sheet explains why the study is being carried out and what it will involve – please take the time to read it carefully and feel free to discuss it with others if you wish. Part one tells you about the purpose of the study and what will happen if you take part. Part two contains more detailed information about the conduct of the study.

If you have any questions the research team will be happy to discuss the study further – contact details are at the end of the leaflet.

Thank you for reading this

**Part One**

**What is the Study about?**

This study has been set up to explore the quality of life of patients with prostate cancer before and after treatment. This study is designed to collect this information by patients completing questionnaires electronically and to investigate whether this approach could be used in the future for both research and standard medical care. You do not need to be familiar with tablet computers to take part in the study, we will provide support to help you complete the questionnaires.

**Why have I been invited to take part in the study?**

You are starting treatment for prostate cancer.

**Do I have to take part?**

Taking part in the study is entirely voluntary and whether or not you choose to take part will have no influence on your ongoing care. If you do decide to take part in the study you are still free to withdraw from the study at any time without giving a reason. Again, this will have no impact on your ongoing care.

**What does the Study involve?**

The study involves completing questionnaires about symptoms related to prostate cancer and treatment and quality of life. We will also ask you some questions about how much you use computers.

We will ask you to complete the questionnaires before you start treatment and after 3 months. The questionnaires will be completed electronically on a tablet computer when you attend the outpatients department.

We anticipate that it will take 20 – 30 minutes to complete the questionnaires.

After you complete the questionnaires we would like to talk to you about how you found the experience, this will involve a conversation, either in person or by phone, with the doctor conducting the research. We anticipate this conversation will take 10 – 15 minutes and it can be arranged at a time that is convenient for you.

Taking part in the study will not involve any additional visits to hospital.

**Will my taking part in the study be kept confidential?**

Yes – information about you collected during the study will be kept strictly confidential.

**What are the possible disadvantages and risks of taking part?**

The study has been designed to try to minimise any inconvenience to you but it is expected that it may take up to half an hourto complete the questionnaires and 15 minutes to discuss what you thought about it – this does not have to be at the same time. You will be reimbursed for any additional parking charges.

It may be that the questionnaires generates negative thoughts and feelings, this is not the intention of the study. If you have any concerns support will be available from the research team.

Please note that your doctor will not be able to see your answers to the questionnaires as they are part of a research study. If you are having problems with symptoms or experiencing poor quality of life then please discuss this with your doctor or a member of the research team.

**What are the possible benefits of taking part?**

There is no direct benefit to you for taking part. However, some patients may feel that completing the questionnaires helps them to identify needs which they can then explore with their hospital team or GP.

This study will provide information to help us to design how quality of life information is best collected and used for patients with prostate cancer. It may also be relevant for patients with other types of cancer and other diseases.

**Part two – Additional information**

**Optional Parts of the Study**

**Electronic consent**

If you agree to take part in the study you will be asked to sign a paper consent form, you will be given a copy of this for your records. We are also investigating whether it is feasible to give consent electronically. You can choose to also complete an “electronic consent form” which will be in the form of the same consent form on a tablet computer. You will also be asked a few questions about how you feel about the electronic consent process.

**Optional completion of questionnaires separate from clinic visits**

All participants will be asked to complete questionnaires when they attend clinic at the start of treatment and after 3 months. We are also interested to see whether it is feasible to collect information about quality of life separate from clinic visits. You can choose to complete the questionnaires at 1 and 2 months after starting treatment. You will not necessarily be seen in clinic at that time but can complete them at home.

You can either complete the questionnaires on your phone or tablet computer (by downloading an “app”) or on a website on a desktop or laptop computer. If you choose to take part in this optional part of the study we will ask for your mobile number and/or email address so that we can send you the link to complete the questionnaires and your username and password. You will be sent reminder text messages or emails to prompt you to complete the questionnaires and remind you of your username and password. You will be given one week to complete them and so can do so at your convenience.

There will be no charge for text messages. If you choose to complete the questionnaires on your phone or tablet we will provide the “app” free of charge. However, you might be charged to download the “app” and upload your answers depending on your phone contract and signal availability. The “app” has been designed to minimise these data charges but we suggest that you download the “app” when you are connected to a free wifi network if possible. If you incur any data charges these will be reimbursed by the research team.

**What happens if I don’t want to carry on with the study?**

You are free to withdraw from the study at any time without giving a reason. This will have no impact on your ongoing care.

**What if there is a problem?**

If you have any concerns about any parts of the study you can speak to the research team who will be happy to meet and discuss your questions. If you remain unhappy and wish to complain formally you can do so through the NHS complaints procedure, each hospital has a patient advice and liaison department (PALS).

**Will my taking part in the study be kept confidential?**

Confidentiality will be regarded at all times. Your questionnaires will be identified by a study number rather than your name. The information you provide will not be shared with your clinical team on an individual basis. If the research team are concerned that you are experiencing symptoms or poor quality of life that might be improved with further support they will contact you directly to ask your permission to contact a member of your hospital team or GP.

Your mobile phone number and/or email address will only be used to send information and reminders as described in this information sheet. It will be kept securely and confidentially.

**Involvement of the General Practitioner (GP)**

We will ask your permission to inform your GP that you are involved in the study. This is because we will check with your hospital team and/or your GP how you are before we send you reminders over the follow-up period.

**What happens to the results?**

The results of the study will be used to inform doctors and the wider NHS about the impact of these treatments on quality of life. This will allow more complete information provision for patients contemplating treatment. The results will presented at conferences and published in peer reviewed journals. No patient –identifying details will be included.

**Who is organising the study?**

Brighton and Sussex University Hospitals Trust is sponsoring the study. A company called Vitaccess has developed the electronic questionnaires and provide the system for completing the questionnaires at home (which is optional) including reminder text messages or emails. The study is being funded by a medical education grant from Sanofi (a pharmaceutical company).

**Have patients and the public been involved in designing the study?**

Representatives from PCaSO – the Eastbourne Prostate Cancer Information and Support Group have been involved in designing the study, testing the electronic questionnaires and reviewing the information sheets.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants rights and wellbeing. This study has been reviewed and given favourable opinion by the South Central – Hampshire-A Research Ethics Committee.

**Who can I contact for more information?**

If you have any questions or would like to discuss this study in more detail then please speak to the research team at your hospital.

**Contact details**

Dr Sally Appleyard

Sally.appleyard@bsuh.nhs.uk

07789 260046

**What happens now?**

You will be given some time to read this information sheet think about the study and discuss it with anyone you like. If you are happy to be involved in the study a member of the research team will ask you to sign a consent form and then complete the initial questionnaires with you prior to your treatment commencing.

**Thank you for taking the time to read this information sheet**