Informed Consent Form for Participation in a Research Study

An electronic treatment decision support tool for prostate cancer patients: a feasibility study

Main Informed Consent Form (Online)

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Contact Information: Please contact Gideon Yang at (416)-946-4501 ext. 3593 or gideonyang@uhnresearch.ca for any questions related to the study. Please note that communication via e-mail is not absolutely secure. Thus, please do not communicate personal sensitive information via e-mail.

INTRODUCTION
You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study’s risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

BACKGROUND
There are four primary treatment options available for men with prostate cancer, which are active surveillance, radical prostatectomy (surgery), external beam radiation, and brachytherapy.

Patients find it difficult to choose from the treatment options for various reasons. The newly diagnosed prostate cancer patients are under high level of anxiety and concerned about the post
treatment quality of life and adverse effects associated with various treatment options. Studies have reported men’s unpreparedness to distinguish between the different treatment options and hence the confidence in choosing between the treatment options. The decision support tool is designed to better prepare the prostate cancer patients by increasing their knowledge about the disease and making appropriate choices for better health and life style. Men who have been recently diagnosed with prostate cancer and have not chosen a treatment option yet are approached to participate in a study.

PURPOSE
The purpose of this study is to evaluate the feasibility of an online decision support tool specifically designed to help men with prostate cancer choose a treatment. Feasibility is the evaluation of a project’s overall potential, including the ability to run such a program within the hospital.

STUDY PROCEDURES
About 120 men who are diagnosed with prostate cancer who have not made the treatment decision will participate in this study. You will be randomly assigned to one of the three groups (two intervention groups and one control group) after you have consented for the study and completed the first set of questionnaires. Randomization means that you are put into a group by chance, like flipping a coin. You will have a 1/3 chance of being placed in any group. Neither you nor your doctor can choose what group you will be in.

If you choose to participate in this study, you will be asked to login to www.ProstateDecision.ca on your personal computer. After reviewing the consent form, you will be required to register for participating in the study. The registration part will comprise of unique ID (please see your flyer), email address and creating a password. Once you have registered, you need not to memorize your unique ID, as your email address will serve as your username. After you have registered on website, you will be asked to complete the first set of computerized questionnaires. The questionnaires consist of demographic information, assessing your prostate cancer knowledge and your level of anxiety and distress. This session will take approximately 10-15 minutes and once you have completed the first set of questionnaires, you will be randomly assigned to one the following three groups:

- **Intervention Group-1**: Participants randomized to Intervention group -1 will have access to a visual version of the decision making tool at the website www.prostatecentre.ca.
- **Intervention Group-2**: Participants randomized to Intervention group -2 will have access to a text version of the decision making tool at the website www.prostatecentre.ca.
- **Control Group**: Participants randomized to the control group will have access to a standard version of the website www.prostatecentre.ca. The website provides disease and treatment specific information for all participants.

You will receive an email one month after consenting to complete the second set of online questionnaires. The questionnaires consist of website interface related questions, assessing your
decisional conflict scale and prostate cancer knowledge. This session will take you about 10 minutes to complete.

You may then have a follow-up appointment with your doctor to make a treatment decision. Three months after receiving the active treatment, you will be asked to complete the third set of questionnaires. These questionnaires will be assessing your anxiety level and your satisfaction level with the decision instrument. This session will take you about 10 minutes to complete.

You will also be contacted by the study coordinator to remind you for completing each set of the questionnaires.

**VOLUNTARY PARTICIPATION**
Your participation in this study will not affect the health care provided to you by UHN. Your participation is completely voluntary. You may decide not to be in this study, or to participate in the study now and then change your mind later. You may leave the study at any time without affecting your care at the University Health Network (including The Princess Margaret Cancer Centre, Toronto General Hospital, Toronto Western Hospital, and Toronto Rehab). You may refuse to answer any question you do not want to answer. If you decide to withdraw from the study, the information that was collected before you leave the study will not be used for analysis without your permission. No new information will be collected after your withdrawal from study.

**RISKS TO PARTICIPATION IN THE STUDY**
There are no known risks to participating in this study, other than the possible feelings that may arise when reviewing cancer diagnosis and treatment options.

**BENEFITS**
The possible benefits for participation in this study include increased understanding of prostate cancer disease characteristics, increased awareness about different treatment choices and their effects on quality of life. Results from this study will help us to develop the decision support tool for men with prostate cancer who are facing difficulty in choosing between treatment options for prostate cancer.

**ALTERNATIVES TO BEING IN THE STUDY**
You do not have to join this study to gain access to the website.

**CONFIDENTIALITY**
If you agree to join this study, the study doctor and his/her study team will ask you to provide personal health information. Only information needed for the study will be requested. Personal health information is any information that could be used to identify you and includes your:

- name,
- address,
- age,
- medical history.
The information that is collected for the study will be kept in a locked and secure area by the Principal Investigator for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records.

Representatives of the University Health Network, including the Research Ethics Board, may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

**COSTS AND REIMBURSEMENT**
You will not have to pay for any of the tools or questionnaires involved with this study. You will not be reimbursed for your time.

**CONFLICT OF INTEREST**
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

**RIGHTS AS A PARTICIPANT**
By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**QUESTIONS ABOUT THE STUDY**
If you have any questions regarding this study or desire further information, you may contact the Study Coordinators; Gideon Yang at (416) 946-4501 extension 2598 or Sarwat Abbasi at (416) 946-4501 extension 3815. You may also contact the Principal Investigator, Dr. Andrew Matthew at (416) 946-2332.

If you have any questions about your rights as a research participant or have concerns about this study please contact the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office at (416) 581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.