Recovery Support for Bladder Cancer Patients and Caregivers: A Multimodal Approach
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Northwell Health

Campus: Arthur Smith Urology Center

Consent for Participation in a Randomized Control Trial

Title: Recovery Support for Bladder Cancer Patients and Caregivers: A Multimodal Approach

Principal Investigator: Michael Diefenbach, Ph.D

Sponsor: Department of Medicine

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions.

This consent form will explain:

- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	The purpose of this research study is to develop and evaluate a comprehensive multimodal approach to bladder cancer recovery focusing on both patients and caregivers before and after treatment.
What will happen to me during the study?	You will be "randomized" into one of the research study groups described below. Randomization means that you are put into a group by chance; it's like flipping a coin. For both groups, the pre-treatment education (Module 1) will be completed by a qualified healthcare professional any time before surgery. The content of Module 1 is the same for both groups and consists of the

	standard of care, pre-surgery education that all patients undergoing bladder removal surgery receive. Therefore, Module 1 can be completed before or after enrolling in this study. If you are in **group 1**, you will have an in-person or remote visit which will involve completing a survey, and receiving the post-treatment research material (Module 2). The material for Module 2 includes a link to the web-based application and a unique username and password. Module 2 contains several hours of material focused on improving overall health post treatment. Information of study Module 2 can be accessed from any device (mobile phone, tablet, or desktop computer). To access Module 2, participants in group 1 may be given a personal tablet (Samsung Galaxy Tablet), with internet access for the duration of the study ONLY IF they do not have a personal device (e.g., computer, phone) to use to at home. Only 1 tablet will be given per patient/caregiver pair. If you are in **group 2**, you will partake in an in-person or remote visit which will involve completing a survey, and receiving the post- treatment research material (Module 2). The Module 2 material for group 2 is an extensive brochure which contains material focused on general wellness and caregiver support. In both groups, we will review your medical records to assess your baseline information (which are questions relating to your cancer diagnosis and treatment). Following the in-person or remote visit, you will be contacted and asked to complete follow-up assessments at four time points (1, 3, 6, and 12 months after treatment).
How long will I participate?	You will participate for one year.
Will taking part expose me to risks?	Some of these questions we will ask you may make you feel anxious or uncomfortable. If this happens you do not need to answer these questions. You have the right to withdraw at any time during the study. In the unlikely event that you feel very distressed, we will refer you to a licensed social worker from our institution. There is also the risk of a breach of confidentiality, however the research team has put measures in place to keep your personal information safe and reduce the risk of a breach.
Are there any benefits to participation?	This research will not benefit you directly. However, information we learn about the program or condition may help patients in the future.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Why is this research study being done?

The purpose of this research study is to develop and evaluate a comprehensive multimodal approach to bladder cancer recovery focusing on both patients and caregivers before and after treatment. You are being asked to participate in this study because you or the person you are caring for has recently completed treatment for bladder cancer (BC).

How many people will take part in this study?

This research study hopes to enroll 287 patients and caregivers overall. We hope to enroll 97 individuals at this site for this phase of the study.

How long will you be in this study?

If you choose to take part in this study, the study procedures will last for 1 day (50-60 minutes), and you will be followed for an additional 12 months.

What will happen in this research study?

You will be "randomized" into one of the research study groups described below. Randomization means that you are put into a group by chance; it's like flipping a coin. A computer program will place you in one of the research study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

For both groups, the pre-treatment education (Module 1) will be completed by a qualified healthcare professional any time before surgery. The content of Module 1 is the same for both groups and consists of the standard of care, pre-surgery education that all patients undergoing bladder removal surgery receive. Therefore, Module 1 can be completed before or after enrolling in this study.

If you are in **group 1**, you will have an in-person or remote visit which will involve completing a survey, and receiving the post-treatment research material (Module 2). The material for Module 2 includes a link to the web-based application and a unique username and password. Module 2 contains several hours of material focused on improving overall health post treatment.
Information of study Module 2 can be accessed from any device (mobile phone, tablet, or desktop computer). To access Module 2, participants in group 1 may be given a personal tablet (Samsung Galaxy Tablet), with internet access for the duration of the study ONLY IF they do not have a personal device (e.g., computer, phone) to use to at home. Only 1 tablet will be given per patient/caregiver pair.

If you are in **group 2**, you will partake in an in-person or remote visit which will involve completing a survey, and receiving the post- treatment research material (Module 2). The Module 2 material for group 2 is an extensive brochure which contains material focused on general wellness and caregiver support.

In both groups, we will review your medical records to assess your baseline information (which are questions relating to your cancer diagnosis and treatment). You will be asked about your age, race, marital status, household income, and education, and about some of your medical conditions.

Following the in-person or remote visit, you will be contacted and asked to complete follow-up surveys at four time points (1, 3, 6, and 12 months after treatment). Surveys will be Internet-, mail-, or telephone-based and will be conducted by the Research Assistant.

Additionally, if you are randomized to group 1, the study coordinator will contact you between the 6 month and 12 month time points to schedule a time to return the tablet. The tablet must be returned within a month of the 12 month time point.

What are the risks of the research study? What could go wrong?
Some of these questions we will ask you may make you feel anxious or uncomfortable. If this happens you do not need to answer these questions. You have the right to withdraw at any time during the study. In the unlikely event that you feel very distressed, we will refer you to a licensed social worker from our institution.

There is also the risk of a breach of confidentiality, however the research team has put measures in place to keep your personal information safe and reduce the risk of a breach.

What are the benefits of this research study?
This research will not benefit you directly. However, information we learn about the program or condition may help men in the future.

Are there any costs for being in this research study?
No. You will not have any added costs from being in this study.

Will you receive any payments for participating in this research study?
You will receive a $30 for each completed assessment (baseline, 1-, 3-, 6-, 12-month), for a total compensation of up to $150.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to the IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate.

What information will be collected and used for this study?
If you agree to be in this study we will collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information that identifies you in the form of a limited data set collected from this research study with:

- Investigators at Fox Chase Cancer Center/Temple University

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from Federal and state government oversight agencies, such as the Department of Health and Human Services and the National Institute of Health.
- Representatives from the Northwell Health's Research Protection Program (a group of people that oversee research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it will be released to others.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Michael Diefenbach Ph.D
Northwell Health
Center for Health Innovations and Outcomes Research
600 Community Drive, Suite 403
Manhasset, NY 11030

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Michael Diefenbach at (516) 600-1440. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Witness's Printed Name

_____ _____
Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name