The Ottawa Hospital | L'Hôpital d'Ottawa

INFORMATION SHEET AND CONSENT FORM

The Prehabilitation Study:
Exercise before Surgery to Improve Patient Function in People with Cancer

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Funding Agencies: The International Anesthesia Research Society
The University of Ottawa Anesthesia Research Grant

INTRODUCTION / BACKGROUND

You are being asked to participate in this study because you are at least 60 years of age and you are or are soon to be scheduled for intra-abdominal or intra-thoracic cancer surgery.

Before you make your decision, it is important for you to understand what the research involves. This information sheet and consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. Please take time to read the following information carefully and discuss it with your family and/or friends before you decide.

WHY IS THIS STUDY BEING DONE?

People aged 60 years and older are the fastest growing part of the population and undergo surgery at a higher rate than any other age group. This is of particular concern as frailty becomes more common with advancing age. Frailty is a condition that describes the build-up of weakness across multiple body systems, and is a known risk factor for unfavorable outcomes after surgery.

Given the high rate of frailty, and the strong link between frailty and how patients do after surgery, the care of older patients who demonstrate frailty has been identified as a key area of focus to improve the quality of care for people having surgery. Specifically, the role of exercise before surgery (prehabilitation) is a priority for patients, clinicians, and the healthcare system. Our plan is to explore the usefulness of a home-based prehabilitation program.

To answer these questions, the Departments of Anesthesiology, Surgery, and Geriatrics with the assistance of the Faculty of Health Sciences will be doing a study of patients before and after surgery. We will compare the results between those who participate in a home-based prehabilitation program before surgery to those who do not.

HOW IS THE STUDY DESIGNED?

Our study is a two-group, randomized, controlled, single-blind trial. This means that you are put into a group by chance (like flipping a coin). Neither you, nor the research team can choose the group you will be in. You will have an equal (50:50) chance of being assigned to either of the

programs (the intervention program or control program). The purpose of randomization is to ensure that those receiving the study intervention and those who are not are identical in every other respect, or at least any differences are accounted for when it is time to look at the results. That way, we can be sure that any differences we observe between the two groups are due to the study intervention and nothing else.

WHAT IS EXPECTED OF ME?

Before Your Surgery

You will be asked to complete a standardized set of paper-based questionnaires to document your own report of your health status. We will also measure your function with a 6-minute walk test and a short physical performance measure which includes a chair stand, balance tests, and walking speed. We will also ask you if you have any fear of falling. Altogether, this should take approximately 30-45 minutes of your time.

You will be asked if you wish to complete the 6-minute walk test with sensors attached to your body to measure the way you walk and the way you hold your body. It is entirely your choice to do the 6-minute walk test with or without the sensors.

If you are randomized to the interventional group (the prehabilitation program); you will be asked to complete 1-hour prehabilitation sessions a minimum of 3 times per week. The prehabilitation sessions include walking for exercise, and strength and flexibility training. You will be provided with a pedometer for walking and an elastic resistance band for the strength and exercise training. In-person teaching sessions will be provided at The Ottawa Hospital, but you will also be sent home with a video tutorial on the exercises in the event that you cannot attend the teaching sessions. You will also be sent home with nutritional advice. You will be asked to complete daily logs of your activity. A research team member will phone you once a week to ask you how you are doing with the program, what exercises you have completed, if you have attended a teaching session or watched the video, if you have experienced any discomforts or challenges with the program or have experienced any extra concerns about falling. During the last phone call before your surgery, you will be asked to answer a few additional questions to better understand your experience with the program. This will take about 10 minutes of your time. Your responses to some of these questions will be audio-recorded for research analysis purposes only. The research assistant will inform you when the recording starts. Your recordings will be kept confidential.

If you are randomized to the control group, you will be provided the exact standard of care as per our hospital practice. You will receive the pamphlet: 'World Health Organization (WHO) Global Recommendations for Physical Activity for Health for People 65 Years and Above', as well as Canada's Food Guide.

Regardless of what group you are assigned to, all of your in-hospital care around the time of surgery will be in accordance with our hospital standards as prescribed by your surgeon and anesthesiologist.

Day of Your Surgery

All aspects of your medical, surgical and anesthetic care will be routine and will not be affected in any way by your participation in this study.

After your surgery

A trained research assistant will review your hospital chart to determine your date of hospital discharge and to document whether you had any complications.

The research assistant will call you 30 days after surgery to ask you a few questions over the phone and to see how you have been feeling since your surgery. These will be the same set of questions that you answered at the cancer assessment clinic before your surgery.

On the day of your standard surgical follow-up appointment, approximately 30-45 days after surgery, a research assistant will meet with you to complete the same set of the function tests that you did before surgery (6-minute walk test and short physical performance measures). The research assistant will phone the necessary administrative staff to confirm your scheduled appointment time. If you chose to wear the sensors during your initial 6-minute walk test, you will be asked if you could wear them again at this time point.

If you were randomized to the intervention group, you will be asked to bring your activity logs to this follow-up appointment so the research assistant can file them accordingly.

Lastly, a research assistant will phone you 90 days after surgery to ask you the same set of questions that you had previously answered on the iPad, but this time it will be over the phone. To remind you, these questions will ask you about your health status and fear of falling.

If you are in hospital at the time of the 30 and 90 day calls, the research assistant will call you in hospital or will meet with you in person if you are at The Ottawa Hospital in order to ask you these questions.

HOW LONG WILL I BE INVOLVED IN THE STUDY?

Your participation will begin at the time of your routine surgical consultation, and will conclude 3 months after your surgery.

WILL MY RESEARCH DATA BE USED IN FUTURE RESEARCH?

The data collected from the current study will not be used in future research.

POTENTIAL RISKS AND/OR DISCOMFORTS

There is no added risk related to being in this study. The questionnaires and function tests will take some added time during your clinic visits. You are able to skip any questions and any aspects of the function test that you do not feel comfortable with.

In order to be cleared for surgery, you had to pass a pre-operative functional status evaluation. The exercises in the prehabilitation program are associated with much less risk than surgery, suggesting that you are also qualified to participate in the prehabilitation program.

However, exercise can be associated with heart and breathing problems, especially if you haven't exercised regularly and start out with exercises that are too intense. For this reason, our recommended activities allow you to gradually increase your intensity over time.

However, if you ever experience chest pain or have serious shortness of breath during or after exercise you should seek emergency medical help. If you are randomized to the control group, there are no foreseeable risks involved for not participating in the prehabilitation program, as you will receive the same care that you would get if you were not in the study.

POTENTIAL BENEFITS

We are encouraged by the previous research to date which suggests the usefulness of prehabilitation before surgery. Therefore, if you are randomized to the intervention group, you may benefit in terms of how well you do after surgery, though this is not yet conclusive. Furthermore, some research has found that for those who are frailer, exercise may decrease the risk of falls.

VOLUNTARY PARTICIPATION & WITHDRAWAL

Your participation in this research study is entirely voluntary. You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw at any time. This will not affect your present or future care at The Ottawa Hospital. You may also choose not to answer any specific questions. The study doctors may also decide to discontinue the study at any time, or withdraw you from the study, if they feel that it is in your best interests or if your surgery ends up not taking place for any reason. If you choose to enter the study and then withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis, however no further information will be collected from the time of withdrawal, onward.

NEW INFORMATION

You will be advised of any new information during this study that may affect your desire to remain in the study. If more effective techniques become available, they will be offered to you.

COMPENSATION

In the event of a study-related injury you will be provided with appropriate medical treatment and care. Financial compensation for lost wages, disability or discomfort due to an injury is not generally available. You are not waiving any of your legal rights by agreeing to participate in this study. The study doctor and The Ottawa Hospital still have their legal and professional responsibilities.

WILL I BE PAID FOR MY PARTICIPATION OR WILL THERE BE ANY ADDITIONAL COSTS TO ME?

You will not be paid for participating in this study. However, your hospital parking will be reimbursed since your hospital visits will be longer in time as a result of being in the study.

CONFIDENTIALITY

- All information collected during your participation in this study will be identified with a unique study number, and will not contain information that identifies you, such as your name, address, etc.
- The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave this site.
- Any documents leaving The Ottawa Hospital will contain only your unique study number. This includes publications or presentations resulting from this study.
- The audio-recording of the interview done before your surgery will be sent to an off-site company to be transcribed into a written document. The audio file will be password protected and encrypted. The person assigned to transcribe your interview will not be told your identity.
- Information that identifies you will be released only if it is required by law.
- For audit purposes only, your original medical records and study records may be reviewed under the supervision of Dr. McIsaac's staff by representatives from:
    - the Ottawa Health Science Network Research Ethics Board (OHSN-REB),
    - the Ottawa Hospital Research Institute
- Research records will be kept for 10 years, after this time they will be destroyed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This research study can be found on the above listed website by using the clinical trial registration number NCT02934230.

QUESTIONS ABOUT THE STUDY

If you or your family members have any questions, if you feel that you have experienced a study-related injury or if you desire further information about this study before or during participation, you may contact Dr. Dan McIsaac at 613-798-5555, extension 18253.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. The Board considers the ethical aspects of all research studies involving human participants at The Ottawa Hospital. If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, extension 16719.

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Consent to Participate in Research

- I understand that I am being asked to participate in a research study about the usefulness of a home-based prehabilitation program on outcomes after surgery.
- This study was explained to me by _____.
- I have read, or have had read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

_____ _____ _____

Participant's Printed Name Participant's Signature Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____ _____ _____

Investigator/Delegate's Printed Name Investigator/Delegate's Signature Date

Assistance Declaration

Was the participant assisted during the consent process? ❑ Yes ❑ No

❑ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, and consent was freely given by the participant/substitute decision-maker.

❑ The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the participant/substitute decision-maker, and believe that the participant/substitute decision-maker has understood the information translated.

_____ _____ _____

Name of Person Assisting (Print) Signature Date