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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: The Prehab Study- Pre-operative Rehabilitation for reduction of Hospitalization After coronary Bypass and valvular surgery.

Principal Investigator: **Dr. Rakesh Arora MD PhD FRCSC FACS**
Research Director – Section of Cardiac Surgery
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Co-Principal Investigator:

Dr. Todd Duhamel PhD
Associate Professor
Faculty of Kinesiology & Recreation Management
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Dr. Ansar Hassan MD PhD FRCSC
Assistant Professor
Department of Cardiac Surgery
Dalhousie University

Dr. Nicholas Giacomantonio MD FRCPC
Associate Professor of Medicine
Dalhousie University

Co-Investigators:

Dr. Navdeep Tangri, Dr. Thang Ngoc Nguyen, Dr. Sarvesh Logsetty, Dr. Jitender Sareen, Dr. Colleen Metge, Dr. Hillary Grocott, Dr. Jo Anne Sawatzky, Dr. Kenneth Rockwood, Dr. Sean Bagshaw, Dr. Jonathan Afilalo, Dr. Jean-Francois Legare

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You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family or (if applicable) your doctor before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information you do not clearly understand.

Purpose of the Study

This research study is being conducted to evaluate the effects of pre-operative exercise and education on the outcomes of elective cardiac surgery. The primary purpose of this study is to establish the safety of this program and evaluate the length of stay in hospital following surgery. A total of 244 patients will be recruited to participate in this study.

This study has been registered on a publicly available registry databank. ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Study Procedures

In this study, you will be randomized into one of the 2 study groups described below. Randomized means that you are put into a group by chance, like flipping a coin. You will have an equal chance of being placed in either group.

Standard Care Group Procedures:

If you are eligible for the 'current standard care' group, you will be asked to complete the following 9 appointments with the Research Assistant over a period of approximately one year:

Appointment #1/2: These appointments will take place within the next week and you will be asked to come to the St. Boniface Hospital (Winnipeg, MB). During the first appointment, you will undergo a detailed frailty assessment, a graded exercise test, and complete a 6-minute walk test. The frailty assessment will involve a variety of questions, in addition to several tests of physical function including a chair-stand test, balance tests, and grip strength. For the 6-minute walk test you will be asked to walk in a hallway, at your own pace, for a total of 6 minutes. This simple test will provide information regarding your physical fitness level; it is routinely used for clients participating in

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cardiac rehabilitation programs across Canada. The Research Assistant will also provide you with a Physical Activity Monitor, which is a small device that is about the size of a watch and is worn on a belt. This device measures the amount and intensity of physical activity that you complete on a daily basis. Given the small size and placement of the accelerometer at belt level, you will be able to participate in your normal daily routine without alteration. It is important to note that the monitor will only measure the amount of physical activity that you accumulate and does not store personal information. Therefore your privacy will not be adversely affected by wearing the unit. The monitor will be given to you by the research staff at each of the three meetings and you will be asked to return the unit to the St. Boniface Hospital seven days later. At the second appointment, you will be asked to complete a series of questionnaires. Each of these appointments will take approximately 1 hour of your time.

Appointment #3: this appointment will occur approximately 4-6 weeks following initial randomization to the intervention or control group. During this appointment, the Research Assistant will provide you with a Physical Activity Monitor; you will be asked to wear this monitor for a period of 7 days. This part of the pro-operative assessment appointment will take approximately 30 minutes of your time.

Appointment #4/5: these appointments will be combined with your cardiac surgery pre-operative appointment at the St. Boniface Hospital, approximately 1 week prior to your surgery. During the fourth appointment, you will be asked to undergo a detailed frailty assessment and the 6-minute walk test. The Research Assistant will also provide you with a Physical Activity Monitor; you will be asked to wear this monitor for a period of 7 days. At the fifth appointment, you will be asked to complete a series of questionnaires. Each of these appointments will take approximately 1 hour of your time.

Appointment #6/7: about 3 months after your surgery, the Research Assistant will contact you to make two appointments to come back to the St. Boniface Hospital. During the sixth appointment you will undergo a detailed frailty assessment and the 6-minute walk test. The Research Assistant will also provide you with a Physical Activity Monitor; you will be asked to wear this monitor for a period of 7 days. At the seventh appointment, you will be asked to complete a series of questionnaires. Each of these appointments will take approximately 1 hour of your time.

Appointment #8/9: about 1 year after your surgery, the Research Assistant will contact you to make two appointments to come back to the St. Boniface Hospital. During the eighth appointment you will undergo a detailed frailty assessment and the 6-minute walk test. The Research Assistant will also provide you with a Physical Activity Monitor; you will be asked to wear this monitor for a period of 7 days. At the ninth appointment, you will be asked to complete a series of questionnaires. Each of these appointments will take approximately 1 hour of your time.

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Intervention Group Procedures:

If you are randomized to the intervention group, you will be asked to complete the same 5 appointments outlined for the standard care group above. In addition, you will be asked to participate in the "Pre-hab Program for Cardiac Surgery Patients" at your local, community-based cardiac rehabilitation facility. This unique program has been developed to meet individualized exercise and educational needs of patients waiting for cardiac surgery. Before you start the program, you will receive a baseline health and fitness assessment by the cardiac rehabilitation centre staff. This assessment includes a questionnaire, a graded exercise test, lung function test, body measurements (waist, hip and body weight) and a blood test (glucose and lipid levels). The Research Assistant will also collect these results as part of the study.

The education part of the pre-hab program will be made up of a series of 4 classes at your local, community-based cardiac rehabilitation facility. The goal of these classes is to help you to make improvements and/or changes in your lifestyle. Topics for these classes include self-management strategies for cardiac rehabilitation: risk factor reduction, medication use, cardiovascular physiology, stress management, healthy eating and promotion of self-managed care.

The exercise part of the pre-hab program will consist of an individualized exercise program, based on your health assessment. If you choose to participate in the study and are randomized to the intervention group, we will request that you commit to attending your local cardiac rehabilitation facility for 2 supervised exercise sessions each week until you are called for your surgery or for the duration of your 8-week program. We will also ask you to keep a record of your visits to the facility.

There will be NO cost to you for participating in the exercise program, other than your time and your transportation costs.

All Study Participants: If you agree to participate in this study, we will also be obtaining information from your hospital chart. This will include information about your past medical history and details regarding your surgery/hospital stay. Participation in the study will continue for approximately 1 year after your cardiac surgery. If you are interested in receiving a summary of the study results, please designate on this form below.

Risks and Discomforts

The risks to participating in this research are considered to be minimal. However, there is a certain degree of risk involved in the initiation of any exercise program. If you are randomized to the intervention group, you will be carefully assessed by the medical fitness facility staff prior to the initiation of an exercise program. Additionally, the symptom limited, graded program of exercise would be individualized according to your personal health status. Although the exercise classes will be conducted by certified and

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experienced instructors, if you have reason to believe that you would be at physical risk of harm/injury by participating in the program, you are asked to decline participation in this project. The cardiac rehabilitation has trained exercise specialists on site to supervise the exercise programs offered at the facility. Additionally, trained healthcare personnel are also on site at all times. The researcher may decide to take you out of this study if your health status changes to prevent you from being able to continue to participate. For example, if your heart condition gets worse before your surgery, it may not be appropriate for you to continue participating in the study. Your participation in the study may also be discontinued upon the advice of a medical doctor.

Benefits

There may or may not be direct benefit to you from participating in this study. We intend to use the information learned from this study to benefit other individuals who are awaiting cardiac surgery in the future.

Costs

All procedures, which will be performed as part of this study, are provided at no cost to you. The cost to you will be transportation to St. Boniface Hospital for the assessment appointments.

Confidentiality

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba.

Organizations that may inspect and/or copy your research for quality assurance and data analysis include groups such as: The University of Manitoba Health Research Ethics Board or the St. Boniface Hospital Office of Clinical Research.

All study related documents will bear only your assigned study number. All data will be entered into a computer and transmitted electronic to members of the research team only. All hard copy records will be kept in a secure area and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave St. Boniface Hospital. If deemed necessary by the research staff, information regarding your health status may be shared with medical staff at the St. Boniface Hospital.

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Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. However, if you decide to stop participating in the study, we encourage you to discuss this decision with the research study staff first. There are no consequences to withdrawing from the study. Your decision not to participate or to withdraw from the study will not affect your care at this centre. If the study staff feels that it is in your best interest to withdraw you from the study, they will remove you without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to remain in this study.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact Dr. Rakesh Arora at (204) 258-1031 or bpambrun@sbgh.mb.ca.

For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389. Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this information/consent form. I have had the opportunity to discuss this research study with Dr. Rakesh Arora and/or his staff. I have had my questions answered by them in a language I understand. This risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor, or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board and the St. Boniface Hospital Office of Clinical Research for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

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Should you be deemed not safe for participation in PREHAB, would you be willing to be contacted to enroll in our registry study where you will only be asked to complete telephone questionnaires at 3 and 12 months after your surgery?
YES _____ NO _____

I would like to receive a summary of the study findings
YES____ NO____

If YES, please provide mailing or e-mail address:

_____

Participant printed Name: _____

Participant signature: _____ Date: _____
(day/month/year)

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

Printed Name: _____ Date:_____
(day/month/year)

Signature: _____ Role in the study: _____

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