Effect of an Exercise Rehabilitation Program on Symptom Burden and Quality of Life in Hemodialysis: A Randomized Controlled Trial

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Effect of an Exercise Rehabilitation Program on Symptom Burden and Quality of Life in Hemodialysis: A Randomized Controlled Trial.

Principal Investigator: **Dr. Clara Bohm BScH, MD, MPH, FRCPC**
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Co-Investigators: Dr. Todd Duhamel, Dr. Navdeep Tangri

Sponsors: **University of Manitoba and Kidney Foundation of Canada**

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 determine if a self-management education program that includes physical activity promotion, a structured exercise program at a certified medical fitness facility, plus cycle-exercise during dialysis improves the number and severity of symptoms experienced by hemodialysis patients.

Study Procedures

In this study, once you sign consent you will be asked to complete a survey that records the number and severity of symptoms you have had over the past week. If you score 0 (have no symptoms) on this survey, you will not be eligible to participate in this study. If your score is more than 0, 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 4 appointments with the Research Assistant:

Appointment #1: The baseline appointment will take place at your hemodialysis unit prior to your dialysis treatment on a mid-week dialysis day. Prior to this appointment, the Research Assistant will visit you during your dialysis treatment and describe the project procedures to you and ensure that any/all of your questions are answered. The Research Assistant will provide you with a study information sheet and ask you to provide written consent. The Research Assistant will give you a time and date to attend the baseline appointment and leave you with a series of questionnaires (looking at your symptoms and physical activity level and quality of life) that you will fill out and bring with you to the baseline appointment. The Research Assistant will also provide you with a Physical Activity Monitor (accelerometer), which is a small device that is about the size of a watch and is worn on a belt. You will be asked to wear this monitor for a period of 7 consecutive days. 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 while wearing the device. 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 prior to each of the four appointments and you will be asked to bring the unit in with you to each of your study assessment appointments, which will take place at your usual hemodialysis unit prior to your normally scheduled dialysis treatments. . At this first appointment, you will be asked to complete several physical tests. This appointment will take approximately 30 minutes of your time.

Appointment #2: This appointment will occur approximately 12 weeks (3 months) after you have started the study and will be at your hemodialysis unit prior to your dialysis treatment on a mid-week dialysis day. Prior to this appointment, the Research Assistant will visit you during your dialysis treatment and give you a time and date to attend appointment #2. The Research Assistant will also leave you with a series of questionnaires to fill out and a Physical Activity Monitor to wear for 7 days. You will be asked to bring both the questionnaires and the Physical Activity Monitor to your appointment #2. At this appointment you will hand in all questionnaires and the Physical Activity Monitor as well as complete several physical tests. This appointment will take approximately 30 minutes of your time.

Appointment #3: This appointment will occur approximately 26 weeks (6 months) after you have started the study and will be at your hemodialysis unit prior to your dialysis treatment on a mid-week dialysis day. Prior to this appointment, the Research Assistant will visit you during your dialysis treatment and give you a time and date to attend appointment #3. The Research Assistant will also leave you with a series of questionnaires to fill out and a Physical Activity Monitor to wear for 7 days. You will be asked to bring both the questionnaires and the Physical Activity Monitor to your appointment #3. At this appointment you will hand in all questionnaires and the Physical Activity Monitor as well as complete several physical tests. This appointment will take approximately 30 minutes of your time.

Appointment #4: This appointment will occur approximately 52 weeks (12 months) after you have started the study and will be at your hemodialysis unit prior to your dialysis treatment on a mid-week dialysis day. Prior to this appointment, the Research Assistant will visit you during your dialysis treatment and give you a time and date to attend appointment #4. The Research Assistant will also leave you with a series of questionnaires to fill out and a Physical Activity Monitor to wear for 7 days. You will be asked to bring both the questionnaires and the Physical Activity Monitor to your appointment #4. At this appointment you will hand in all questionnaires and the Physical Activity Monitor as well as complete several physical tests. This appointment will take approximately 30 minutes of your time.

As part of the standard care group you will also be asked to keep track of any exercise you do using an exercise log sheet that the study kinesiologist will collect weekly.

Intervention Group Procedures

If you are randomized to the intervention group, you will be asked to complete the same 4 appointments outlined for the standard care group above and keep track of any physical activity you do outside of the structured program using an exercise log sheet that will be provided to you . In addition,

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you will be asked to participate in a structured exercise program specifically designed to increase your level of physical activity.

To help identify the intensity at which you should start exercising, you will attend an appointment at the Wellness Institute or at your dialysis unit where you will exercise on a stationary bicycle with gradually increasing workload for as long as you can comfortably do so. This appointment will take approximately 30-60 minutes.

As part of the study, you will be required to participate in supervised exercise on a stationary bicycle during your dialysis treatments. The program itself will consist of 60 minutes of continuous cycling exercise at a pre-determined intensity during each dialysis session for 26 weeks. You will also receive standardized education and resistance training sessions during your hemodialysis sessions during the first 8 weeks of the intervention. After this, you will be provided with materials to continue resistance exercises two times per week for the remainder of the intervention period at your home at a time that is convenient for you.

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

Risks and Discomforts

The risks of 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 dialysis unit physicians and staff prior to initiation of the exercise program. Additionally, the gradually increasing program of exercise will be modified to be appropriate for your personal health status.

Monitored exercise is very low risk. Exercise has been shown to be safe in hemodialysis in other studies. However, when starting any exercise program it is possible that you could:

- **Have muscle or joint soreness after exercise, especially if you have not exercise recently**
- **Have low blood pressure on hemodialysis after exercising**
- **Develop or have worsening chest pain (angina) during or after exercise (low risk)**
- **Develop an irregular or fast heart rate rhythm during or after exercise (low risk)**
- **Develop a heart attack during or after exercise (low risk)**
- **Have low sugars during or after exercise if you have diabetes. It is important to monitor your sugars closely when starting any exercise program.**
- **There is a small risk of tendon rupture**
- **There is a very small risk of death related to the above side effects if they occur**

Although the exercise instructions will be provided by certified and 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. Additionally, trained healthcare personnel are also on site at all times. The researcher may decide to take you out of this study without your consent if your health status changes to prevent you from being able to continue to participate. 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 patients receiving hemodialysis to treat common symptoms and help them to become more physically active.

Costs

All procedures, which will be performed as part of this study, are provided at no cost to you. If you are randomized to the intervention group, a possible cost to you will be transportation stationary cycling test at the Wellness Institute. However, this cost will be subsidized at the amount of $20 per assessment. In addition, you will receive $20 in reimbursement at each study assessment visit you attend to help with transportation costs which you might incur due to the need to be there earlier than normally scheduled for your dialysis.

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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 Biomedical Research Ethics Board and 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 electronically 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. No information revealing any personal information such as your name, address or telephone number will leave the Health Sciences Centre, St. Boniface Hospital, or Seven Oaks General Hospital. If deemed necessary by the research staff, information regarding your health status may be shared with medical staff at the Health Sciences Centre or Seven Oaks General Hospital.

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 study staff feels that it is in your best interest for you to withdraw 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 Monica Sharma at (204) 633-3667 or msharma7@exchange.hsc.mb.ca, or Dr. Clara Bohm at (204) 631-3834 or cbohm@exchange.hsc.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. Clara Bohm and/or her 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 for quality assurance purposes.

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

I agree to be contacted for future follow-up in relation to this study – 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 signature: _____ Date: _____
(day/month/year)

Participant Printed Name: _____

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: _____

ALL SIGNATORIES MUST DATE THEIR OWN SIGNATURE.

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