Participant Information and Consent Form

Title: Pole Walking Intervention within Independent Living/Retirement Communities: Feasibility and Pilot

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Sponsors: Saskatchewan Health Research Foundation (SHRF) and Saskatchewan Centre for Patient-Oriented Research (SCPOR)

Introduction

You are invited to take part in this research because you are living in an independent living/retirement community. The study will examine the feasibility of pole walking intervention within independent living/retirement communities, and if pole walking intervention can improve your physical activity, physical function, body composition, fear of falling and quality of life and decrease your sedentary time.

Your participation is voluntary. It is up to you to decide whether or not you wish to take part. If you decide to participate, you are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to participate, you will not affect your relationship with the researchers, Forever…*in motion* program or University of Saskatchewan

Please take time to read the following information carefully. You can ask the study staff to explain any information that you do not clearly understand. You may ask as many questions as you need. Please feel free to discuss this with your family, friends or family physician before you decide.

Who is conducting the study?

The study is being funded by the Saskatchewan Health Research Foundation (SHRF) and Saskatchewan Centre for Patient-Oriented Research (SCPOR). The SHRF and SCPOR will reimburse the investigators and university for the costs of undertaking this study. However, neither the institution nor any of the investigators or staff will receive any direct financial benefit from conducting this study.

Why is this study being done?

Aging and inactivity can weaken muscles and bones and impair physical function, mobility and balance. Walking with poles, combined with muscle strengthening and balance exercises, offers an attractive activity format for adults 50 years and older to increase physical activity and improve function. It is unknown if pole walking is a feasible activity format for residents living in the independent living/retirement homes. It is also unknown if participation in pole walking intervention in the independent living/retirement communities would improve participants' physical activity, physical function, body composition, fear of falling and quality of life and decrease their sedentary time. This study is being done to provide this information.

Who can participate in this study?

You are eligible to participate in this study if you are living in an independent living/retirement community and you are physically inactive. You cannot take part in the study if you are using assistive devices for mobility, diagnosed with Parkinson's disease or currently participating in moderate-to-vigorous-intensity exercise training, including pole walking (same as Nordic walking) more than 150 minutes per week.

We will determine whether exercise training is safe for you by having you fill out a brief questionnaire (the Get Active Questionnaire). If there is doubt about the safety of exercise participation for you based on this questionnaire, we will need to get permission from your family physician before you can participate in this study.

What does the study involve?

Your independent living/retirement community will be first randomized (i.e., assigned by chance, by a computer) into a pole walking group or a control group. Then, participants in both groups will have study measurements at the first week. After the first week measurements, pole walking group will have exercise sessions either indoors or outdoors, two to three times per week, for 20-60 minutes per session, over a 12-week period at their independent living/retirement community. Control group will continue life as usual during this 12-week period. Then, participants in both groups will have follow-up measurements after the 12-week period.

After the follow-up measurements, control group will also be offered the same pole walking intervention (i.e., exercise sessions either indoors or outdoors, two to three times per week, for 20-60 minutes per session, over a 12-week period) at their independent living/retirement community.

The pole walking sessions will be done in small (<10 participants) groups. In the first exercise session, you will receive a pair of poles, and learn to set them for your height. Each session includes a warm-up, strengthening and dynamic balance and stretching exercises as part of the walking sessions. Training sessions will be tailored for each individual. Pole walking time and number of repetitions will be increased when your function improves during the intervention. Sessions will be led by trained peer/staff/student instructors.

We invite you to participate in the following measurements at the College of Kinesiology labs (University of Saskatchewan) at the first week and after 12 weeks:

1. You will be asked to participate in a "Timed up and go" test. The test starts in a seated position. You will be asked to stand up and walk 3 meters, turn around, walk back to the chair and sit down. The researcher will first demonstrate the test. After a practice trial, the researcher will measure the time you took to complete the test. This test will be completed three times.
2. You will be asked to walk for 6 minutes. The researcher will measure your walking distance in 6 minutes time.
3. You will receive bone density scans (dual energy X-ray absorptiometry, DXA scanner) of your hip, spine and total body. The DXA scanner measures body composition, including bone mineral, fat and lean tissue mass. There will be a total of 3 scans: whole body, hip, and spine. This should take under 20 minutes. You will need to remove any metal such as buttons/zippers, so please dress accordingly.
4. You will be asked to participate in a 30-second sit-stand test, where the researcher will count how many times you stand up from the chair in 30 seconds.
5. Your hand strength will be measured using a special device called a handheld dynamometer. You will be asked to squeeze the device as hard as you can for 3 seconds.
6. You will receive images of your forearm and lower leg at two sites with a peripheral quantitative computed tomography (pQCT) scanner. The pQCT is an imaging tool that uses a low dose of X-ray radiation to assess bone and muscle size, geometry

and composition at the forearm and lower leg. Your arm will be scanned on the wrist and the forearm and the leg will be scanned on the ankle and calf. A total of 4 scans will be performed with pQCT with each scan taking approximately 90 seconds. We will assess your bone properties, including strength and measure your arm and leg muscle size and composition from these images.

7. We will give you a total of six questionnaires. These questionnaires ask about your medications and health, nutrition, fear of falling, quality of life and feedback related to the pole walking intervention. Questionnaires will take about 20-60 minutes to complete and you can fill them out at home and bring them to your measurement session or your pole walking instructor, or mail them to us. You may choose to not answer any question(s) you do not want to answer.
8. We will fit you with an Actigraph accelerometer, which is a small device that records your physical activity levels and is worn on your right hip. We will ask you to wear the accelerometer for 7 days. An instruction/recording sheet will be sent home with you. A research assistant will collect the accelerometer and recording sheet 7 days after the testing session, or you may mail it to us.

The total time for these measurements will be about 2 hours.

Please also note that there is an optional photo and video taking for you during this study for publication purposes. Your face will be censored and will not be recognized by the public. You can opt-in or out of this option at the end of this form.

What are the benefits of participating in this study?

You may not benefit from this study. You may improve your mobility or muscle strength by participating in pole walking intervention, but these benefits are not guaranteed.

What are the possible risks and discomforts?

The exercise may result in muscle pulls or strains, or muscle soreness. You will be given a warm-up prior to exercising and qualified exercise trainers will supervise training sessions. Adequate rest will be given between training and testing sessions to ensure that your muscle is recovered by the next training session. Training will initially be quite light and we will gradually increase the amount of training done per session over the first couple of weeks of training to allow your muscles to get used to the training and minimize muscle soreness. There is a small amount of radiation exposure from the DXA and pQCT scans.

This is equal to the amount of radiation you would receive during 1 day from natural sources and is about one-third of the dose of radiation you would receive during a cross-country airplane flight.

Please note that the research site is located at the University of Saskatchewan and your Independent Living/Retirement Communities, under the jurisdiction of the Saskatchewan Health Authority. We are taking appropriate safety precautions to reduce the risk of the spread of COVID-19 and expect you to do the same. Researchers will keep you informed and up to date on COVID-related safety requirements and information that may affect your participation (for example, contact information and contact tracing, if applicable).

What are alternatives to the study?

You do not have to participate in this study to perform the pole walking exercise. Pole walking poles can be purchased, and information on supervised training programs are available at RUH via Forever…*in motion* program.

What happens if I decide to withdraw?

Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. Your relationships with the researchers or the university will not be affected. If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment will be retained for analysis.

What happens if something goes wrong?

In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the principal investigator. Inform the medical staff you are participating in a clinical study. Necessary medical treatment will be made available at no cost to you. By signing this document, you do not waive any of your legal rights against the sponsor, investigators or anyone else.

What happens after completion of the study?

Please provide your email at the end of this form if you want to receive your test results and the publication of the study findings.

What will the study cost me?

You will not be charged for the training or any research-related procedures. You will not be paid for participating in this study. Reimbursement for parking costs to participate in the measurements at the University of Saskatchewan is available.

Will my participation be kept confidential?

In Saskatchewan, the Health Information Protection Act (HIPA) defines how the privacy of your personal health information must be maintained so that your privacy will be respected. We will use study code number rather than personal information to keep your personal information confidential. Your name will not be attached to any information, nor mentioned in any study report, nor be made available to anyone except the research team. Because of the group training, other participants will know you are in the study, and we will ask all of the participants to respect the identity of other participants and keep names confidential. It is the intention of the research team to publish results of this research in scientific journals and to present the findings at related conferences, but your identity will not be revealed.

Your contact information will be kept in a secured location separate from your data. Group emails will not be sent, nor mass mail outs, to protect your identity. You will be assigned a code that will be kept separate from your personal information and consent form. Your screening and consent forms will be kept in a locked cabinet in a lab at the College of Kinesiology, University of Saskatchewan. All your digital data will be recorded on a secure password-protected, restricted access server drive on the University of Saskatchewan's internal server. Excel files of your data will be encrypted, and password protected. Your data will be kept on the server for a minimum of five years after the study is completed and data has been published. Only researchers approved for this study will be able to have access to your data.

Who do I contact if I have questions about the study?

If you have any questions or desire further information about this study before or during participation, you can contact Saija Kontulainen at (306) 966-1077 or saija.kontulainen@usask.ca

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Chair of the University of

Saskatchewan Research Ethics Board, at *306-966-2975 (out of town calls 1-888-966-2975)*. The Research Ethics Board is a group of individuals (scientists, physicians, ethicists, lawyers and members of the community) that provide an independent review of human research studies. This study has been reviewed and approved on ethical grounds by the University of Saskatchewan Research Ethics Board.

CONSENT TO PARTICIPATE

- o I have read (or someone has read to me) the information in this consent form.
- o I understand the purpose and procedures and the possible risks and benefits of the study.
- o I have been informed of the alternatives to the study.
- o I was given sufficient time to think about it.
- o I had the opportunity to ask questions and have received satisfactory answers.
- o I am free to withdraw from this study at any time for any reason and the decision to stop taking part will not affect my future relationships at the university.
- o I agree to follow the principal investigator's instructions and will tell the principal investigator at once if I feel I have had any unexpected or unusual symptoms.
- o I have been informed there is no guarantee that this study will provide any benefits to me.
- o I will receive my test results and the publication of the study findings by providing my email address.
- o I give permission for the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.
- o I understand that by signing this document I do not waive any of my legal rights.
- o I will be given a signed and dated copy of this consent form.
- o My family physician can be informed about my participation in this study, and, if required, consulted regarding my health and treatment.
  - ❑ Yes, you may contact my primary care physician
  - Name_____ Contact information: _____
- o Permission to be contacted for future studies
  - ❑ I agree to be contacted for future research that evolves from the outcome of this project.
- o Permission for visually recorded images/data
  - ❑ I agree to have photos and videos taken of me.
- o I agree to participate in this study:

Printed name of participant: _____

Signature _____

Date_____

Printed name of person obtaining consent:_____

Signature _____

Date_____

If you are interested to receive article of study results, please provide your email:

Email: _____