**Participant Information and Consent Form**

**Title:** Nordic walking for individuals with osteoporosis, vertebral fracture or hyperkyphosis

**Principal Investigator:** Saija Kontulainen, Professor, College of Kinesiology, University of Saskatchewan, phone: 966-1077

**Co-Investigators:** Philip Chilibeck, Professor, College of Kinesiology; J.D. Johnston, Professor, College of Engineering; Kasie Kelln, Family Physician, Saskatoon Health Region and College of Medicine; Karen Levesque, Director, Seniors Health, Saskatoon Health Region; Stephan Milosavljevic, Professor, College of Medicine; Kevin Spink, Professor, College of Kinesiology; Kimberly Willison, Royal University Hospital and Saskatoon Health Region; and Jenny Basran, Geriatrician, Associate Professor, Saskatoon Health Region and College of Medicine; Suelen Meira Goes, Postdoctoral Fellow, College of Kinesiology.

**Research Coordinator:** Chantal Banda, College of Kinesiology

**Sponsor**: Saskatchewan Health Research Foundation (SHRF), Saskatchewan Centre for Patient-Oriented Research (SCPOR), and RUH Foundation

**Introduction**

You are invited to take part in this research because you are an adult with osteoporosis and past vertebral fracture or hyperkyphosis. The study will assess the safety and the efficacy of a Nordic walking intervention on mobility, physical function, posture and quality of life in individuals who have osteoporosis, a history of vertebral fracture or hunched-back posture (hyperkyphosis).

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, Saskatoon Health Region, RUH 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), Saskatchewan Centre for Patient-Oriented Research (SCPOR), and RUH foundation. The SHRF, SCPOR and RUH foundation will reimburse the investigators and university for the cost 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?**

As we age, our muscles and bones become weaker. In osteoporosis, low bone mass and weak bone structure make bones prone to fractures. Weaker back muscles provide less support to the spine and that can also contribute to fractures in the spine. The objective of this study is to determine the efficacy of a Nordic walking intervention on mobility, physical function, posture and quality of life. The study will also assess the safety of Nordic walking by recording any injuries during the intervention. Both the benefits and safety are important to know to justify and modify recommendations of Nordic walking therapy for individuals with osteoporosis, history of vertebral fracture or hunched-back posture (hyperkyphosis).

**Who can participate in this study?**

You are eligible to participate in this study if you have been diagnosed with osteoporosis, past vertebral fracture or hyperkyphosis. You cannot take part in the study if you are currently participating in moderate-vigorous exercise training, including Nordic walking more than once per week. We will invite 80 women and 50 men to participate in this intervention.

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?**

If you agree to participate in the study you will be randomized (i.e. assigned by chance, by a computer) into one of two groups: Group 1 is a Nordic walking group and will exercise three times per week over 3-month period. Group 2 is a Control group and will continue life as usual without changing exercise habits. Participants in both Groups will have study measurement baseline and after 3 months. Group 2 (Control group) can participate in the Nordic walking sessions after their control period and have follow up measurements afterwards. You will have an equal chance of being assigned to either of the two groups. During the COVID-19 pandemic, participants will complete an additional follow up assessment by filling questionnaires and measuring the physical activity level as performed in the two previous evaluations.

The Nordic Walking training will be done in small (~10 participants) group sessions three times per week for 3 months. In the first session, you will receive a pole set for your height. You will practice Nordic walking technique and receive an individual program that will be first shorter in duration and progress every week up to 60 minutes/session. Each session includes a warm-up, strengthening and dynamic balance and stretching exercises as part of the walking sessions. Training sessions will be led by a trained peer- and student-instructors. Group sessions of individually tailored training will be offered at Market Mall, or with the option of remote participation from home, or a park nearby Market Mall.

We will invite you to the following measurements in the Market Mall Community Health Centre, nearby public park or College of Kinesiology lab:

1. You will receive a dual energy x-ray absorptiometry (DXA) scan of your hip, spine (including vertebral fracture assessment) and total body. We measure areal bone density of your hip to diagnose osteoporosis, and to total body scan provides your lean and fat tissue mass.
2. We will obtain images forearm and lower leg at two sites with a peripheral quantitative computed tomography (pQCT) scanner. 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 estimate your bone strength and measure your arm and leg muscle properties from these images.
3. 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 walks 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.
4. You will be asked to walk for 6 minutes. The researcher will measure your walking distance in 6 minutes time.
5. 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.
6. 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.
7. We will measure your posture by measuring the angle of your upper back using two tools called Kyphometer and spinal mouse.
8. We will give you six questionnaires. These questionnaires ask about your medications and disease, nutrition, fear of falling, exercise confidence, functional status, quality of life, and loneliness. Questionnaires will take about 20-60 minutes to complete and you can fill them home and bring to your measurement session, your Nordic walking instructor, or mail it to us. You may choose to not answer any question(s) you do not want to answer.
9. 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.

We will try to do all the six lab measurements mentioned above in one visit. The total time for these lab measurements will be about 2 hours.

**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 Nordic walking, 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.

**What are alternatives to the study?**

You do not have to participate in this study to perform the Nordic walking exercise. Nordic 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 study-related expenses (e.g. travel, parking, meals) is not 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, 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.

**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 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-*966-4053 (out of town calls 1-888-966-4053)*. 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**

* I have read (or someone has read to me) the information in this consent form.
* I understand the purpose and procedures and the possible risks and benefits of the study.
* I have been informed of the alternatives to the study.
* I was given sufficient time to think about it.
* I had the opportunity to ask questions and have received satisfactory answers.
* 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.
* 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.
* I have been informed there is no guarantee that this study will provide any benefits to me.
* I will receive my test results and the publication of the study findings by providing my email address.
* I give permission for the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.
* I understand that by signing this document I do not waive any of my legal rights.
* I will be given a signed and dated copy of this consent form.
* My family physician can be informed about my participation in this study, and, if required, consulted regarding my health and treatment.

q  Yes, you may contact my primary care physician

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Permission to be contacted for future studies

q  I agree to be contacted for future research that evolves from the outcome of this project.

* Permission for visually recorded images/data

q  I agree to have photos and videos taken of me.

* 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 you email:

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_