*This sample is for researchers to use as a guide in developing their study materials. Instructions to the researchers are written* *in* ***[square brackets in bold italics]*** *and should be deleted. Instructions that are* *in* ***[square brackets, bold italics, and are blue]*** *need to be replaced with details specific to the study and changed to* black, un-bolded, un-italicized*, and removed from square brackets before uploading the material to the research ethics application.****Please also delete this instructional paragraph.***

**\*\*Please review the Guide to Creating an Information Letter and Consent Form for additional details\*\***

## Participant Information Sheet and Consent Form

**Project Title: *[insert title]***

**Primary Investigator:** ***[insert name, affiliation, phone, University of Waterloo email address]***

**Co-investigators: *[insert names]***

**Students or Trainees**: ***[insert name(s)]***

**Sponsors:** ***[insert sponsor(s)]***

This letter explains what the study is about, possible risks and benefits, and your rights as a research participant. You may print/save a copy for your records. If you do not understand something in the letter, please ask one of the investigators before consenting to participate.

**Introduction**

You are being invited to participate in a research study. We have outlined the study here and will discuss it with you. Please read this information carefully. Ask questions about anything that you want to know more about.

**Why is this research being done?**

Exercise is often recommended to those with osteoporosis. There are very few studies that examine how effective and safe it is for people with spine fractures to participate in exercise.

**What is the study’s purpose?**

Our team wants to investigate whether exercise can improve health and prevent fractures in individuals who have had a spine fracture. We need to do a study to achieve this goal. The current study will recruit 160 women with spine fractures at eight centres in Canada and Australia. It will be the first step in finding out if it is feasible to do such a study. The current study will also help us understand whether exercise can improve function and quality of life for women with spine fractures.

**What will your responsibilities be if you decide to participate?**

You will be asked to participate in one visit to St. Mary’s General Hospital at the beginning of the study, and one visit at the end of the study, or twelve months later. Each study visit will take approximately two hours and will include the assessments listed below. If you cannot complete an assessment, or do not wish to, you can remain in the study. The only assessments that are mandatory are the X-ray, memory tests and medical history at the start, to confirm that you are eligible to participate.

*Study assessments during study visits at the start and 12 months later:*

* X-rays of your spine to confirm the number and severity of fractures. If you have had spine X-rays in the last 3 months, we will examine those; otherwise, we will have a new x-ray taken.
* A physical assessment that includes assessing your height, your balance, your posture, your walking speed over 4 meters, and your back and arm endurance. Balance tests include a measure of how far forward you can reach with your arm, how many times you can step on a block with your foot in 15 seconds, your ability to stand with your eyes closed, and how well you can get out of a chair 5 times or get out of a chair and walk three feet and come back to the chair. The posture assessment requires you to stand against the wall and have your height and the distance between your head and the wall measured. The back and arm endurance test requires you to hold two 2-pound weights straight out in front of you for a maximum of 2 minutes.
* The researchers will review your medical record to obtain the date of your most recent spine fracture, and for any measurements of vitamin D that were performed.
* You will be asked to wear an activity monitor for 7 days at the beginning and end of the study.

*Other assessments:*

* You will be provided with monthly calendars to keep track of your activity, whether you have had a fall, and whether you are taking your osteoporosis-related medication (if applicable) or used any health care services.
* You will be contacted half-way through the study to complete questionnaires over the phone. The questionnaires will ask about your health, your physical activity level, the health services you use, your physical function and perceived quality of life.
* You will be contacted monthly to see how you are doing, and whether you have had any illnesses or injuries. If you have, you may be asked questions about the injury or illness, and any health services you used. A phone number will be provided so that you can report any falls, injuries, or health problems.
* If you experience a bone fracture at any point during the study, we will ask for access to your medical records to see the X-rays and details about the fracture.

Everyone in the study will be provided with a years’ supply of vitamin D supplements (1000IU per day, in the form of Ddrops). All participants will be visited in home by the study physical therapist six times over the twelve-month study period. Each home visit will be approximately 45-60 minutes. Once you complete the first study visit, you will be randomly assigned to one of two groups. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers can choose what group you will be in. Participants in Group 1 will be given an exercise program during the home visits with the physical therapist, as well as an exercise band and exercise materials. The exercise program will be tailored to individual ability and will include aerobic, strength and balance training to be performed at least three times weekly. Participants in Group 2 will receive educational materials and will discuss general health or other topics during the home visits. They will receive a tailored exercise program identical to that received by participants in Group 1, and all the exercise materials 12 months later. You will be asked not to disclose what group you are in to the research assistant performing assessments.

**What are the benefits of the study for me and/or society?**

We will provide you with the results of your assessments at the end of the study so that you can see how you did. You will be allowed to keep all the exercise materials and you will receive an exercise program from a physical therapist. We will host a social event and information session at the end of the study that you can attend if you wish. Our study will be a first step in providing more evidence about the safety and effectiveness of exercise in women with spine fractures.

**What are the possible risks and discomforts?**

There is a potential for exercise-related changes to occur during the assessments or exercise, such as muscle soreness and changes in blood pressure and heart rate. Any physical exercise or performance-based test is associated with a risk of falls or cardiovascular complications. We aim to minimize the risks by having the exercise prescription done by a physical therapist, and by having training for our staff. The X-rays involve exposure to radiation. The total dose at each of the two visits is approximately 3.2 mSv. For perspective, we are exposed to ~3mSv of natural background radiation each year. Radiation exposure can have a cumulative impact so if you are concerned you can discuss the risks with your physician.

We are asking you to be on 1000IU of vitamin D for the duration of the study (or remain on the vitamin D regimen recommended by your doctor if the dose is higher). Although significant side effects have not been reported when vitamin D is taken as directed, you should notify your doctor and the study staff immediately if you have any of the following: bone pain, muscle pain, nausea or vomiting, constipation, diarrhea, loss of appetite, metallic taste, dryness of mouth, weight loss, increased thirst, increase in amount and frequency of urination especially at night, cloudiness or protein in the urine, irregular heartbeat, headache (continuing), drowsiness, unusual tiredness or weakness, calcium deposits (hard lumps) in tissues outside of the bone, itching of skin, loss of sex drive, mood or mental change, increased sensitivity of eyes to light or irritation of eyes, redness or discharge of the eye, eyelid, or lining of the eyelid, and runny nose.

**What information will be kept private and confidential?**

Your data will not be shared with anyone except with your consent. All personal information will be removed from the data and will be replaced with an ID code. Your information will be stored at the study site as well as on a virtual (online) system that is managed by EmPOWER Health Research in London, Ontario. The system is secure, and it encrypts the data and protects it with a password that is only known by the research team. Paper and electronic records will be retained for ***[insert time period]*** after the study is complete, and study data will be retained for 25 years. All anonymized forms and study data will be stored on a password-protected online database. Only the research team will have access to the data. Some of the data may be examined by students doing thesis projects or research internships, but your name or other identifying information will not appear. You can request your data be removed from the study up until ***[insert date]*** as it is not possible to withdraw your data ***[insert reasoning e.g., data is anonymized, papers and publications have been submitted to publishers, etc.]***. ***[If data may be shared in an online repository, please see the ICL guide for details about what information and language to include]****.*

Information about you will be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorized representatives of the University of Waterloo Research Ethics Board or as required by law. By signing the Consent Form, you authorize release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published or presented in a variety of forums. The results will be presented in such a way that you cannot be identified, except with your permission. You may be asked if you would like to have your photo taken during study activities for use in presentations, training information or publications. This is voluntary and not a requirement of the study. If you are to be photographed, you will be asked to sign a separate consent form.

Information about your participation in this research project may be recorded in your health records.

**Can I end my participation early?**

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether you take part or not. If you volunteer to be in this study, you may withdraw at any time. If you withdraw, you will be asked if there are some parts of the study you are still willing to complete (e.g., phone assessments only). You can opt out of only some parts of the study or withdraw altogether. We will not withdraw previously collected data unless you request that we do. If you decide to withdraw from the project, please notify a member of the research team. If you wish to withdraw your study data after participating, please contact the researchers. Data cannot be withdrawn after results have been published.

**Will I receive anything for participating in the study?**

We will reimburse parking or bus transportation costs for travel to study visits. If you do not have access to transportation, we will pay for a taxi within a reasonable distance from our centre.

**What happens if I have a research-related injury?**

If you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigators, institutions and/or sponsors from their legal and professional responsibilities. If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

If you have any urgent medical problem, injury or illness that is related to your participation in this study or have any questions, concerns or would like to speak to the study team for any reason please call:

Day Emergency Number: ***[insert name of Principal Investigator]*** at phone 519-888-4567 ext. ***[insert ext.]***

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB ***[####] [Replace#### with the file number that is listed at the top of your ethics application]***). If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca.

This project has also been reviewed by, and received ethics clearance through, the ***[insert name of Research Ethics Board]***. If you have any comments or concerns resulting from your participation in this study, you can contact them at ***[insert telephone number and email]***.

For all other questions contact ***[insert researcher name and contact information].***

**Consent of Participant**

I have read the information presented in the information letter about the study, ***[insert title of study]***, being conducted by ***[insert name of Principal Investigator]*** and colleagues or I have had it read to me in a language that I understand. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I requested. I understand the purposes, procedures and risks of the research described in the project.

I am aware that I may withdraw from the study at any time by advising the researchers of this decision.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB ***[####] [Replace#### with the file number that is listed at the top of your ethics application]***). If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca.

This project has also been reviewed by, and received ethics clearance through, the ***[insert name of Research Ethics Board]***. If you have any comments or concerns resulting from your participation in this study, you can contact them at ***[insert telephone number and email]***.

For all other questions contact ***[insert researcher name and contact information].***

With full knowledge of all foregoing, I agree, of my own free will to participate in this study. I have been advised that I will receive a signed copy of this form.

Name of Participant

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Signature of Participant Date

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Person obtaining consent:

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

|  |  |  |
| --- | --- | --- |
| Name, Role in Study | Signature | Date |

Name of Translator, if applicable Language translated into

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Signature of Translator  *Date*

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***[Please check that all relevant study details are included, changes are made to the document to accurately describe the study and procedures, and delete the instructional text printed in bold italics before submitting to the Office of Research Ethics for review.]***