 ****

**Participant Information Sheet and Consent Form** **– Interviews and Focus Groups**

**(BoneFIT Participants)**

**Title of project:** Too Fit to Fall or Fracture: Translating research into practice for fall and fracture prevention

**Primary Investigator:** Lora Giangregorio

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**Student Investigator:** Caitlin McArthur

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**Funding:** Ministry of Health and Long Term Care, Health System Research Fund

**Introduction**

You are being invited to participate in a research study. We have outlined detailed information about the study in this information letter and consent form, and will discuss it with you. Please read this information carefully and ask questions about anything you want to know more about.

**Why is this research being done?**

We want to develop tools and resources to help health care providers, patients and community programs implement physical activity recommendations. We have done extensive research and developed exercise recommendations for fall and fracture prevention. We want to get your input on how we can help you use the recommendations.

**Who qualifies for this study?**

We would like to recruit physicians, physiotherapist, specialists, and community groups who manage individuals with osteoporosis, and people with osteoporosis.

**What will your responsibilities be if you decide to take part in the study?**

If you volunteer to participate in the study you will be asked to participate in a presurvey (online or on paper), and either an interview or a focus group discussion.

1. Surveys: You may have already completed this survey online or via paper. If you have not, you will be asked to complete a survey about your confidence related to exercise and osteoporosis, the recommendations you normally give, your willingness to participate in the study further and some demographic information. If you indicate, we will send you a follow-up survey at a later date very similar to the first survey.

2. Summary: You may be asked to read a one page summary of exercises and physical activity recommendations.

3. Focus group: You will attend a focus group with a group of your peers, and will be asked to identify your needs, barriers and facilitators to implementing exercise recommendations for fall and fracture prevention into practice, addressing gender- or sex-specific needs, the acceptability and applicability of recommendations, and participate in brainstorming on how to promote better use of community resources and implementation of research into practice. The focus group will take approximately 1-2 hours.

4. Interview: An investigator will interview you individually, either in person or over the phone. The investigator will ask you about the emerging roles of allied health providers in interdisciplinary chronic disease management in primary care. The interview will take approximately 1-2 hours.

All focus groups and interviews will be audio recorded and transcribed. If you do not wish to answer a question please state you do not wish to answer. If you would like to say something that you do not want recorded please inform the researcher and we will turn off the audio recording. Given the group format of this session we will ask you to keep in confidence information that identifies or could potentially identify a participant and/or his/her comments. You may be contacted for a follow-up interview to review the results for agreement.

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

You will receive information about the newly released physical activity recommendations, and will learn about currently available tools and resources. This study will provide valuable information that will be used to inform the development of additional tools and resources related to exercise or physical activity.

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

There are no foreseeable risks or discomforts associated with this study.

**How many people will be in this study?**

We will be recruiting 10-15 people from each of the following groups: patients, physicians, community program leaders, physiotherapists/kinesiologists/allied health professionals. We will do this in 7 different regions in Ontario.

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

Your participation is VOLUNTARY. You may withdraw from the study at any time. If you do not wish to answer a question you can leave it blank or state you do not wish to answer it. Participation will not be anonymous as your email address will be retained and you may be contacted for follow-up surveys. However, we would like to assure you that all information you provide will be fully confidential and will be pooled with information from others who will take part. In other words, your responses will not be identified and cannot be traced back to you. Anything deemed private will be removed. Only the research team will be able to link your identity to your answers. The data will be stored on Canadian FluidSurveys servers as well as on secured computers and in locked file cabinets, within a secure area, only available to team members at the University of Waterloo. The fax machine for returned surveys is in a locked area at the University of Waterloo, which is only accessed by two administrative assistants and faxes will be delivered directly to Lora Giangregorio. The data will be stored for 7 years in accordance with University of Waterloo policy 8 (<https://uwaterloo.ca/secretariat/policies-procedures-guidelines/policy-8>). 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. By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

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.

**Can I end my participation early?**

Participation in this research is voluntary. If you do not wish to take part, you do not have to. If you choose to participate 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., one-on-one interview). We will not withdraw partially collected data unless you request that we do. The investigators may withdraw you from this research if circumstances arise which warrant doing so. If you decide to withdraw from the project, please notify a member of the research team.

**Will I be paid to participate in this study?**

You will not be paid to participate in the study. Refreshments or food may be provided during the discussion.

Bone Fit workshop registration fees in the amount of $100 (one day) and $200 (two days) will be reimbursed to those who participate in the study, which includes the pre-survey (online), and either an interview or a focus group discussion session.

If you have any questions regarding this study please contact Caitlin McArthur at 1-519-888-4567 ext. 38779 or cmcarthu@uwaterloo.ca.

This project has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee. Should you have comments or concerns resulting from your participation in this survey, please contact the Director in the Office of Research Ethics at 1-519-888-4567 ext. 36005. You can also contact the Hamilton Integrated Research Ethics Board Manager at 905-521-2100 ext. 42013.

**PARTICIPANT COPY**

**Consent of Participant**

I have read the information presented in the information letter about a study being conducted by Dr. Giangregorio and colleagues. 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 am aware that I may withdraw from the study without penalty at any time by advising the researchers of this decision. This project has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee.

I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact Dr. Maureen Nummelin, Director, Office of Research Ethics at 519-888-4567 ext. 36005 or by email at maureen.nummelin@uwaterloo.ca. You can also contact Deborah Mazzetti, Manager, Hamilton Integrated Research Ethics Board (HIREB) at 905-521-2100 ext. 42013 or by email at mazzedeb@hhsc.ca.

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.

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

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.

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

**INVESTIGATOR COPY**

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Signature of Participant Date

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