INFORMATION SHEET

Project Title

“LIFTMOR: Lifting Intervention For Training Muscle and Osteoporosis Rehabilitation”

Investigators

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Background
As a person ages there is a gradual decline in bone health and an increased risk of falling which, when combined, increases the risk of fractures. This study will help to determine if high-load resistance training or a home-based exercise program are safe and effective strategies for improving bone strength, body composition and physical function in post-menopausal women.

Method
Who:
• Healthy women over 60 years of age

What:
• You will be randomly assigned to either a high-load resistance training program or a home-based exercise program.
• The exercise program will occur twice a week for 8 months.
• Before and after the 8-month exercise period you will be asked to complete:
  o Questionnaires regarding your health, diet and the amount of exercise you undertake
  o Physical tasks including: standing jump, reaching and walking tasks
  o Body composition scans using a dual-energy x-ray absorptiometer (DXA), quantitative ultrasound (QUS) and a peripheral quantitative computed tomographer (pQCT). Those tests are painless and non-invasive but involve either sitting beside or lying still on special scanners for between 3-10 minutes per scan.
• The total time for each testing session will be approximately 2 hours.
• We may video or photograph some activities, but you may opt out of those if you would prefer.

Where:
• For the high-load resistance training program, training will take place at either Southport (Gold Coast), Hendra (Brisbane) or Murarrie (Brisbane), whichever is most convenient for you.
• Testing will occur at Griffith University’s Gold Coast campus (Southport) in the School of Allied Health Sciences.

Inclusion Criteria
You may be eligible to participate in this study if you are over the age of 60 and have low bone mass (we can tell you if you do) and are willing to undertake an 8-month exercise program comprised of two exercise sessions per week.

Exclusion Criteria
You may be excluded if any of the following apply to you:
• Musculoskeletal condition/s preventing physical activity
• Reasons why you cannot participate in vigorous physical activity (i.e. uncontrolled cardiovascular disease)
• Metallic implants (e.g. Staples, joint replacement) or foreign bodies (e.g. shrapnel)
• More than two x-ray examinations in the past year or radiation treatment
• Malignancy
• Mental impairment
• Certain current physical activity
• Medications and/or conditions know to influence bone health (e.g. Paget’s Disease)
Risks
The risks associated with the project are relatively minor. For those unaccustomed to physical activity, it is likely that you will experience muscle soreness following any change in exercise exposure. There is also a risk of injury during exercise. Such injuries are uncommon but may include low back pain, joint sprains, or muscle strains. All physical testing and high-load resistance training will be closely supervised by the investigators to help reduce those risks. If you have low bone mass, you are at greater risk of fracture during heavy lifting exercises than people with higher bone mass. It will be important to perform the exercises as instructed by your trainer to make sure you are doing them safely. Should an injury occur during a study training session, three of the project investigators are physiotherapists who will provide an initial consult and one follow-up consult free of charge at the Griffith University Physiotherapy and Active Health Centre. If further treatment is required, investigators can refer you to an appropriate healthcare professional. The Physiotherapy and Active Health Centre has undertaken to provide discounted rates to physiotherapy patients referred by study investigators.

There are also slight risks associated with some of our tests. DXA and pQCT scans are non-invasive and painless, but they do involve exposure to small quantities of ionising radiation. The amount of radiation exposure during a chest x-ray is 8 times greater than that for either pQCT or DXA tests. The radiation exposure for DXA and pQCT scans is less than 0.01 mSv. For comparison, natural background radiation to which individuals living in developed countries are exposed is estimated to be around 2.4 mSv per year. The exposure to radiation during plane travel is approximately 0.005 mSv per hour, thus a 14 hour international flight from Australia to Los Angeles would expose an individual to approximately 0.07 mSv, or 28 times the radiation from a single DXA scan.

Benefits
- Each participant will receive a free 8-month exercise training program. Each participant will receive free bone, muscle and fat scans and an estimate of calcium consumption.
- Your involvement in this study will help contribute to the understanding of exercise as a treatment strategy for bone health, which will help countless individuals suffering from osteoporosis.

Confidentiality
Results will be kept as confidential as is possible by law and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. All data will be kept in the possession of the investigators. The information collected is confidential and a de-identified copy of this data may be used for other research purposes. You will not be referred to by name during research reports or study discussions. All records will be stored in a locked filing cabinet with restricted access for a minimum of five years in a private office. All computer records will be restricted by password. For further information consult the University’s Privacy Plan at http://www.griffith.edu.au/privacy-plan or telephone (07) 3735 4375.

Use of video recordings and photography
You have an option to consent to being videoed or photographed during the study. Those images or recordings could be used for presentations, media coverage and/or publication of research findings. All material will be stored in a locked file on a password protected computer for a minimum of 5 years.

Contacting the Investigators
We are happy to answer any questions you may have. For general inquiries please contact Mr Steven Watson (student researcher), at steven.watson3@griffithuni.edu.au or on 5552 8281. If you have any concerns with the study, please do not hesitate to contact Dr Benjamin Weeks, on (07) 5552 9336, Dr Sean Horan on (07) 5552 8038, or Assoc Prof Belinda Beck on (07) 5552 8793.

Feedback
Following completion of data collection and analysis, you will be presented with a brief summary of your individual results and, if you’re interested, the overall study findings.

Voluntary Participation
Whether you decide to participate in this study or not, your decision will not prejudice you in any way. If you do decide to participate, you are free to withdraw your consent and discontinue your involvement at any time.

Complaints Mechanism
The University requires that all participants be informed that if they have any complaints concerning the manner in which a research project is conducted they may be given to the researcher, or, if an independent person is preferred: The Manager, Research Ethics, Office for Research, Room 3.60, Science, Engineering and Architecture (G39), Griffith University, Gold Coast campus, Q 4222, Phone: 373 54375 or research-ethics@griffith.edu.au

Please retain this document for your information.
Consent Form

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Consent Statement

By signing below, I confirm that I have read and understood the information package and in particular have noted that:

- I understand that I will be asked to undertake an 8-month exercise program, consisting of 2 sessions per week.
- I understand that will I be randomly assigned to either a home-based exercise program or a high-load resistance training program I understand that there will be a testing session approximately 2 hours in duration both before and after the 8-month exercise period
- I understand that I will undergo dual-energy x-ray absorptiometer (DXA), quantitative ultrasound (QUS) and peripheral quantitative computed tomographer (pQCT) scans and measurement of height and weight to determine body composition;
- I understand that I will be asked to complete several questionnaires relating to physical activity, quality of life, evaluation of the exercise program and diet;
- I understand that I will be asked to perform a series of physical tasks including: standing jump, walking and reaching tasks;
- I have had any questions answered to my satisfaction;
- I understand the risks involved;
- I understand the benefits of my participation in this research;
- I understand that my participation in this research is voluntary;
- I understand that if I have any additional questions I can contact the research team;
- I understand that I am free to withdraw at any time, without comment or penalty;
- I understand that I can contact the Manager, Research Ethics, on 373 54375 (or research-ethics@griffith.edu.au) if I have any concerns about the ethical conduct of the project; and
- I agree to participate in the project.

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(Participant)  (Participant signature)  (Date)

Optional video and photography consent:

☐ I agree to be video recorded while performing the physical activities to be used during presentations, media coverage and publication of research findings.

☐ I agree to be photographed while performing the physical activities to be used during presentations, media coverage and publication of research findings.