A novel exercise treatment to enhance bone strength in the proximal femur.

Department of Mechanical Engineering

Plain Language Statement

We invite you to participate in our research project titled: “A novel exercise treatment to enhance bone strength in the proximal femur”. We would like to give you some background information on why we think this project is important and on what we would like you to do if you decide to join us in this research.

What is the purpose of the study?
The purpose of this study is to determine the effectiveness of intense exercises targeting the thigh and the hip muscles to promote bone strength in the hip. New knowledge regarding the effectiveness of the studied exercise would allow the development of exercise programs to counteract the detrimental effect of osteoporosis.

Who can participate?
You are invited to participate in this project, because you are a female between 18 and 45 years of age, you are able to comprehend written and spoken English, you are able to sustain training programs, and you are conducting a sedentary life style without any current or recent (previous 12 months) participation in high-impact or weight-bearing exercise for more than 1 h/week. We are looking to recruit forty (40) healthy volunteers for this project, half belonging to a group that will undergo a training program (the exercise group) and the other half that will continue a sedentary life style (the control group). All participants must be healthy, conducting a sedentary lifestyle, with no history of stroke or other medical disorders that may have affected their ability to walk, no uncorrected visual disturbances, and no history of highly invasive surgeries such as joint replacements.

What does the project involve?
If you are willing to participate in the study and you are eligible, you will be enrolled in the exercise group or in the control group. The exercise group will undergo six-months training while the control group will continue the usual sedentary life style. Bone strength will be assessed using DEXA exams taken at Western Health and the effect of the exercise will be evaluated by comparing the bone changes measured on the exercise leg, the contralateral leg and the control group. The exercise frequency (no less than four days per week) and the study duration (six months) have been designed to induce perceptible bone changes.

All participants will undergo a first DEXA scan executed upon study commencement and a second scan executed upon study completion. Dual Energy X-ray Absorptiometry, or DEXA scanning, is currently the most widely used method to measure bone mineral density, a parameter that is in strict relation with bone strength. The study will pay for the execution of the DEXA scans at Western Health.
If you are enrolled in the exercise group, you will be asked to undergo six-month unilateral training program using gym machines. During training you will be asked to have suitable attire such as shorts or athletic pants, t-shirt, athletic shoe, and a towel. The type of exercise has been specifically studied to optimise the hip load. At training commencement, you will be instructed on the type of exercise targeting the thigh and the hip muscles you need to perform. The weight you will be asked to lift will be set to 80% of the maximal load you can lift a single time. The weight will be recalculated every two weeks to account for your strength increase. Training will be conducted for no less than four days per week, and the exercise will be repeated 50 times per session, 10 repetitions per set. A single leg will be trained. At the end of each session, you will be asked to fill in a log reporting the day, the weight lifted, and the number of repetitions executed. The log will be collected by the named researchers fortnightly. Therefore, the activities directly supervised by the named researchers will involve 1) taking you through the imaging process at study commencement and completion, 2) providing you clear instructions on the execution of the correct exercise in the gym machine at training commencement, 3) collecting on a fortnightly base the log book, monitoring the execution of the exercise training, redefining the load lifted during the exercise, and monitoring injuries, experience of discomfort and subjective ratings of the intervention. Your responsibility will be to plan the training in a gym of your choice where qualified gym personnel must be present. The study will pay for your gym membership in one of the gyms that are already partner of the study. Other gyms of your choice can also be discussed with the named researchers in terms of distance, cost and the available equipment at the gym.

If you will be enrolled in the control group, you will continue your sedentary life style, and you will be asked to not start any regular (more than 1h/week) intense activity such as running, jumping or lifting weights, for example in a gym. If you will be enrolled in this group, you will be contacted only for the execution of the DEXA scan at project commencement and, after 6 months, for the execution of the DEXA scan at project completion. No other contacts are foreseen, unless you decide to change to a more active lifestyle. This case, you will be required to contact the named researchers and your participation in the study will be ceased.

Are there any potential side effects?

There are known risks and/or side effects associated with the asymmetric nature of the exercise treatment and the X-ray radiation you will be exposed to during the DEXA scans. Every risk is considered minimal due to the study design.

The unilateral resistance training will cause reversible increase of volume and strength of trained muscles potentially causing psychological distress and gait alterations with a possible increase of the risk for injuries during normal ambulatory activities. In fact, the unilateral resistance training is expected to induce a reversible 3-10% increase on muscle volume and up to a 34% increase of muscle strength of the trained muscles, that is, the posterior thigh and hip muscles. Regarding the risk for psychological distress, trained muscles represent approximately one-third of the thigh volume making the expected total changes of the exercise leg volume in the order of a few percentages, ensuring a minimum risk for psychological distress. Regarding the increased risk for injuries, a) the muscle strength unbalance expected from participating in the study (less than 34%) is in the order of what has been observed in healthy and perfectly functional athletes, b) a possible increase for injuries is only hypothetical as the association between bilateral unbalance and a risk for injuries increase has not yet been shown and c) an earlier asymmetric study conducted at the University of Melbourne on a larger cohort of participants has reported no injuries resulting from
the execution of the asymmetric exercise protocol. Therefore, an increased risk for injuries resulting from participating in the study is very unlikely.

To mitigate further the potential side effects from the exercise treatment asymmetry, light symmetric complementary activities, such as cycling or swimming, are recommended during the study, a home-based strengthening exercise for the non-exercised limb is recommended at the conclusion of the study, and participants are recommended to not start an exercise program involving long-distance running/jogging for at least three months following the conclusion of the study.

The DEXA scan will be conducted by an experienced radiographer at Western Health. For the scan, you will lie down on an examining table, and the scanner rapidly directs x-ray energy from two different sources towards your femoral necks, which weakens, or prolongs the transmission of these two x-ray sources. The greater the bone mineral density of your femur, the greater the signal picked up by the sensor reading the x-ray light that passed through your femoral neck. These dependence of the sensor reading by the bone mineral density allows estimating the bone quantity stored in your femoral neck. According to the medical physicist who reviewed this protocol, “this research protocol involves exposure to a very small amount of radiation”. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is less than 0.2 mSv. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure. However, there is the risk that an undiagnosed condition can be detected from your images. Should this happen, your general practitioner will be notified to timely prescribe the most adequate medical treatment.

Additional physical risks for injuries are associated with the execution of intense exercises using gym machines. To minimise the risk, each participant will be clearly instructed by the named researchers on the proper use of the machines and on the proper execution of the exercises. Should any injury occur, qualified gym personnel able to provide first aid assistance will be present.

What if I have any concerns during the study?
The Principal Researcher, Professor Peter Pivonka, will be available if you have any questions. The other investigators will be available if required. This project has been approved by the Human Research Ethics Committee of the University of Melbourne. If you have concerns about the way the study is being conducted, you should contact the Executive Officer, Human Research Ethics, The University of Melbourne, ph: 8344 2073; fax: 9347 6739.

Can I withdraw from the study if I wish?
Your participation in this study is strictly voluntary. You can decide to not take part in the study or to withdraw from the study at any stage of the study. If you decide to withdraw at an advanced stage of the study, you are free to withdraw any unprocessed data previously supplied.

Will my details be kept confidential?
All care will be taken to keep your identity confidential. The co-researcher (Dr. Saulo Martelli) will be responsible for maintaining this confidentiality. A code number and not your name will be used to identify you in this project. We will adhere to the guidelines set out by the National Health and Medical Research Council and the requirements of the Human Research Ethics Committee of the University of Melbourne. However, you must be aware that there are legal limitations to data confidentiality. Furthermore, because the project involves a small number of participants, this may
have implications for protecting your identity; thus, confidentiality cannot be fully guaranteed. All data and reports will be made anonymous and stored in a secure electronic location. Contact details will be entered into secure password-protected files, and hard copies will be destroyed after participant data has been collected. All contact details will be destroyed after five years from study completion.

How do I get more information?
You should ask for any information you want. If you would like more information about the study, or if there is any matter about it that concerns you - either now or in the future - do not hesitate to ask one of the researchers. Before deciding whether or not to take part, you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to do this.

About the researchers:

**Prof Peter Pivoka** is a leader in the area of modelling bone structure, function, and metabolism. He has the necessary experience and skills to provide insights into understanding bone changes following exercise treatments. Phone: 3 8395 8095 email: peter.pivonka@unimelb.edu.au

**Prof Marcus Pandy** is the Chair of Mechanical and Biomedical Engineering in the Department of Mechanical Engineering at the University of Melbourne. He is a world leader in musculoskeletal function and muscle biomechanics. Contact: 8344 4054 email: pandym@unimelb.edu.au

**Prof Peter Ebeling** is a leader in the area of bone structure, function, and osteoporosis assessment and treatment. He has the necessary experience and skills to complete the clinical analysis in this project. Phone: 3 8395 8115 email: peterre@unimelb.edu.au

**Dr Saulo Martelli** is a research fellow in the Medical Device Institute, School of Computer Science, Engineering and Mathematics, Flinders University. He is a researcher in the area of bone and musculoskeletal biomechanics. Email: saulo.martelli@flinders.edu.au

**Dr Hossein Mokhtarzadeh** is a research fellow in the NorthWest Academic Centre at The University of Melbourne. He is a researcher in the area of bone and musculoskeletal biomechanics. Phone: 3 83447776 email: mhossein@unimelb.edu.au