INFORMATION SHEET

Project Title

A comparison of high versus low intensity exercise for symptoms of knee and hip osteoarthritis

Investigators

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Background

Osteoarthritis (OA) of the knee and the hip is a common health issue in the senior population that causes chronic pain, and reduces physical functioning and quality of life. This study will help to determine whether a high or low intensity exercise program is an effective strategy for improving symptoms of hip or knee osteoarthritis and physical function.

Method

Who: Men and women over 50 with knee or hip osteoarthritis

What:

- A 6-month free exercise program
- Volunteers will be randomly allocated to either a twice-weekly, 30 minute, high-intensity progressive resistance training program or, an alternate day, 15 minute low-intensity exercise program
- Before and after the 6-month exercise program:
    - we will assess your height and weight, and your ability in some simple physical tasks such as standing from sitting, reaching, walking
    - you will be asked to complete questionnaires regarding your diet, the amount of exercise you undertake, and your current level of arthritis-related pain, and
    - we will conduct a number of scans on a dual-energy x-ray absorptiometer (DXA). These are painless and non-invasive tests to examine bone, muscle and fat, and involve simply lying on the DXA 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: All testing and the training will take place at The Bone Clinic in Coorparoo (Brisbane)

Inclusion Criteria

You may be eligible to participate in this study if you have knee or hip osteoarthritis and are willing to undertake either of the 6-month exercise programs described above.

Exclusion Criteria

You may be excluded if any of the following apply to you:

- Physical condition/s preventing completion of either exercise program (i.e. spinal cord injury, nerve disorders, uncontrolled cardiovascular disease, etc.)
- Metallic implants (e.g. joint replacement)
- Excessive radiation exposure in the last 12 months (we will assess and advise)
- Malignancy
- Cognitive impairment
- Current regular physical activity similar to either exercise program
- Conditions know to influence bone health (e.g. Paget's Disease, etc.)

Risks

The risks associated with the project are relatively minor. For those unaccustomed to physical activity, some muscle soreness may be experienced following any change in exercise habits. There is also a small 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 minimise those risks. Individuals with osteoarthritis, may be at greater risk of feeling pain during lifting exercises. It will be important to perform the exercises as instructed by your trainer to make sure you are doing them safely and to report discomfort.

There are also slight risks associated with some of our tests. DXA scans are non-invasive and painless, but they do involve exposure to small amounts of ionising radiation. The radiation exposure during all DXA 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 (in other words, 240 times more than all of the DXA scans we will do). The amount of radiation exposure during a chest x-ray is 8 times greater than a DXA scan. 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.

In the event of injury The Bone Clinic procedures will be put in place which includes, depending on the severity of the injury, from least severe to most: first aid, assisting you to organise transport home, or calling an ambulance.

Benefits

- Each participant will receive a free 6-month exercise training program. Each participant will receive bone, muscle and fat scans and an estimate of daily calcium consumption in relation to the recommended amount.
- Your involvement in this study will help contribute to the understanding of exercise as a treatment strategy for symptoms of hip and knee osteoarthritis, which will potentially help countless individuals suffering from the same condition.

What will it cost?

All exercise classes are free. All testing is free with the exception of the DXA scans which are mandatory. Study participants will pay a one-off fee of $165 for baseline and follow-up DXA scans. Travel costs and time away from work will not be reimbursed.

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. A de-identified (meaning you cannot be identified from it) copy of your data may be used in other research analyses. You will not be referred to by name during research reporting. All records will be stored in a locked filing cabinet with restricted access for a minimum of 5 years in a private office. Access to all computer records will be restricted by password. For further information, you may consult the Griffith University Privacy Plan at http://www.griffith.edu.au/privacy-plan or phone 07-37354375.

Use of video recordings and photography

You have an option to decline to consent to being videoed or photographed during the study. Those images or recordings would be used for presentations, media coverage and/or publication of research findings. All images 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 Ms Melanie Fischbacher (project coordinator), at OA@theboneclinic.com.au or on 0468 527 219. You may also contact the other study investigators (details above).

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, including at The Bone Clinic. If you 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, 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 randomly allocated to a 6-month exercise program, of either twice-weekly, 30 minute, high-intensity progressive resistance training or, alternate day, 15 minute low-intensity exercise
- I understand that there will be a testing session of approximately 2 hours in duration both before and after the 6-month exercise period
- I understand that the testing session will involve measures of height, weight, bone, muscle and fat using the techniques described in the information sheet along with a number of questionnaires regarding my diet, the amount of exercise I undertake, my current level of arthritis-related pain, and some simple physical tasks such as standing from sitting, reaching, walking, and, if possible, jumping
- I understand that I will be charge a one-off fee of $165 for the DXA scans required for this study;
- 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.

Participant name	Participant signature	Date

Optional video and photography consent:

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

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

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