Vibration Intervention for Bone, Muscle and Osteoporosis Rehabilitation

INFORMATION SHEET

Who is conducting the research?

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Why is the research being conducted?

In Australia, 1 in 2 women over 60 will suffer an osteoporotic fracture with hip fractures being the most costly and painful. Current treatments are largely limited to medications. Whole body vibration (WBV) is a novel therapy that has been shown to improve bone mass in animal studies. Some human research has also reported promising findings but a large enough study has not yet been conducted to know for sure. Exercise is known to benefit bone, but it is unknown whether it is more or less beneficial than WBV therapy. We have been funded by the government to run such a trial. Specifically, we aim to examine the ability of WBV and/or exercise to reduce the risk of hip fracture.

What will we ask you to do?

You will be randomly allocated to either WBV, a supervised exercise program, a supervised exercise program plus a WBV device, or a home-based exercise program for 12 months.

1. If you are allocated to WBV: The device is slightly larger than a set of bathroom scales and very simple to use. You will be required to stand on it for 10 minutes 5 days per week. It will automatically shut off after 10 minutes. We will bring it to your house and teach you how to use it, and visit you after 6 months to download your first treatment record from the machine. After one year, we will collect the WBV device and you will be asked to revert to your normal daily activities for a further 12 months.
2. If you are allocated to supervised exercise: You will attend two 30-minute sessions per week, for 12 months, at Griffith University.
3. If you are allocated to both WBV and supervised exercise: You will be asked to do both 1 and 2 above.
4. If you are allocated to the home-based exercise program: You will be trained how to do the home exercises, and asked to follow the program twice per week, for 12 months.

Over the course of the first year, periodically you will be invited to morning tea meetings at the Griffith University Gold Coast campus to check how things are going and to record any changes in your lifestyle that might affect your bones. We will provide you with a study diary and ask that you record any falls, fractures, occasions when you visit any health care service, or make any changes to your regular medications, exercise, diet, etc. We will require you to bring the diary with you to the meeting to update our records.

Testing will occur in the Bone Densitometry Research Laboratory (Building G02, Rm 2.08, Griffith University Gold Coast campus, Southport) at the beginning of the study and 12 and 24 months thereafter. Each of the 3 testing sessions will take approximately 2.5 hours. They will include questionnaires about your general health, diet and physical activity, along with physical characteristics such as height, weight, and posture. Bone scans of the whole body, hip, spine, heel, leg and forearm will be performed on special scanning devices. Those tests are painless and non-invasive but you must sit or lie still (for between 3-10 minutes per scan). We will ask you to abstain from taking a calcium tablet 24 hours before your appointment and to remove any metal items, including any clothes containing metal or mineral (e.g. bras with metal clasps, shell buttons, rivets, zips, etc) before being scanned. We have metal free garments you can change into if necessary and a private place to get changed. It will speed up your appointment if you arrive in metal free clothing such as elasticated or drawstring trousers and plain t-shirt, without jewellery.

We will also examine muscle function and balance from some simple painless tests, and perform a standard blood test where we will draw one small (5 ml) tube of blood. The person who will test you is fully trained and experienced in all procedures.

In order to determine any economic benefit of the study interventions, with your permission, we will gather information, including costs, related to any medical care you receive over the 2 year course of your involvement in the study.

Are you eligible?

You may be eligible to participate in the study if you are at least 5 years post menopause and have low bone mineral density (hip BMD t score ≤ -1.0). If you don't have a recent bone scan that shows you have low bone mass, we can scan you to check. We require women whose medication status is very stable. If you ***either*** have not taken any osteoporosis medication (OP meds) in the past 12 months and are not intending to start in the next two years, ***or*** can show evidence that you have been on stable doses of certain bone medications for at least 12 months and plan to continue that therapy for at least two years, you may be eligible. If you are not sure what sort of medication you are taking, we will be able to figure it out from the packaging.

You will not be eligible for the study if you are: less than 5 years post menopause, unable to stand unaided, have used vibration regularly in the last 12 months, unable to understand this information sheet, taking *certain kinds* of bone therapy (some are OK), performing regular high levels of physical activity, have a malignancy, have any conditions (such as thyrotoxicosis or hyperparathyroidism, Paget's disease, renal disease, diabetes, immobility), take other medications known to influence bone health (such as glucocorticosteroids, thyroxine, thiazides or antiretroviral agents), or are unwilling for us to collect information, including costs, related to any medical care you receive over the 2 year course of your involvement in the study. Again, if you are not sure, we can help you determine if any of those criteria apply to you.

Expected benefits

If WBV and exercise reduce the risk of hip fracture, we will have identified an important advance in osteoporosis therapy. If it does not, our research will have ruled out two ineffectual therapies. Either finding has the potential to translate to very large savings in future healthcare costs.

You will personally benefit from your participation by receiving multiple free bone, muscle and fat scans, including a full interpretation of results, to an approximate value of $1000. You will also be provided with a free estimate of your daily calcium consumption and your vitamin D status.

Risks to you

The risks associated with participation in the project are very minor.

Bone, muscle and fat scans

The DXA and pQCT body scans are non-invasive and painless, but they do carry a small degree of risk as they involve exposure to small quantities of ionising radiation. 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 you to approximately 0.07 mSv, or 28 times the radiation from a single DXA scan. The amount of radiation required for a regular chest x-ray is 8 times greater than either of the pQCT or DXA tests.

Blood Sample

Five mls (1 small tube) of blood will be collected by investigators trained in phlebotomy using standard procedures and sterile equipment. There is a small risk of infection during any blood test but the risk can be easily managed by routine procedures. Some people can feel dizzy or nauseous during a blood test. If this happens to you, you can lie down during and after the test and we will keep a check on you for a while to make sure you are alright. You should come to your testing appointment fully hydrated.

Exercise

There is a risk of injury during any exercise. We require you to complete an exercise screening form and will refer you to a doctor for clearance if any conditions are revealed that may put you at increased risk of an adverse event when exercising. If you are not accustomed to exercise, it is likely you will experience some muscle soreness at first. All physical testing and the supervised exercise program will be closely monitored by the investigators to minimise risk and the home exercise program has been designed to be very low risk. Should a study-related injury occur, consultations are available at discounted concession rates at the Griffith Allied Health Clinic.

Whole Body Vibration

The vibration device is very stable and low to the ground so is easy to stand on, but you must take care to use and store it in a location where it will not be a trip hazard. While the manufacturer of the device has collected a large amount of information over the course of many clinical trials, the use of the device has not been evaluated on users with all possible conditions. You should not allow anyone else to use the vibration device as they have not been screened for safety. With your safety as the primary consideration, users with the following conditions or implants should consult their physician before using the device:

- Congestive heart failure
- Past history of deep vein thrombosis and/or pulmonary embolism
- History of thrombophlebitis within 5 years
- Sensitivity to motion sickness
- Known retinal injuries or pathologies
- Orthopaedic implants (e.g. total hip replacement, total knee replacement)
- Pacemakers and Implantable Cardioverter Defibrillators (ICDs)

Feedback to you

You will be presented with a brief summary of your own personal results after each testing session and the opportunity to discuss those results with the investigators. At the end of the study you will be provided with a summary of the overall study findings if you would like.

Your participation is voluntary

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.

Questions / further information

We are happy to answer any questions you may have. If you have any concerns with the study, please do not hesitate to contact any of the research team listed above.

The ethical conduct of this research

Griffith University conducts research in accordance with the *National Statement on Ethical Conduct in Human Research*. If you have any concerns or complaints about the ethical conduct of the research project you should contact the Manager, Research Ethics on (07) 3735 4375 or **research-ethics@griffith.edu.au**.

Privacy Statement – non disclosure

The conduct of this research involves the collection, access and/or use of your identified personal information by the study investigators. On occasion, the investigators may wish to take photographs or audio-visual recordings of study activities, for the purposes of recording study protocols or for presenting the research to other scientists. You may be identifiable from those images. You have an opportunity to provide specific consent to your participation in these kinds of activities. Any additional personal information collected is confidential, will be stored securely, and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes, however, your anonymity will at all times be safeguarded and the data will be destroyed 15 years after completion of the trial. Your blood samples will be stored in a secure freezer until an adequate number of samples have been acquired to run a bulk analysis (likely to be around 6 months), and then discarded. Only the study personnel, and technicians running the vitamin D analysis will have access to those specimens which will be de-identified. For further information consult the University's Privacy Plan at http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan or telephone (07) 3735 4375.

CONSENT FORM

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

- I understand that my involvement in this research will include:

1) random allocation to WBV, or a supervised exercise program, or both WBV and supervised exercise program, or a home-based exercise program for 12 months. I will be required to either: a) stand on the WBV device for 10 minutes per day, 5 days per week, after which time I will return the WBV device and revert to my normal daily activities for a further 12 months; b) undertake a supervised resistance training twice per week for 12 months then return to usual activities for 12 months; c) both "a" and "b"; OR d) undertake a home-based program twice per week for 12 months then return to usual activities for 12 months;
2) a 6 month visit from one of the researchers to my home to check my vibration treatment record;
3) attendance at periodic morning tea meetings in year 1 at Griffith University;
4) recording any falls, fractures, occasions when I visit any form of health care or any changes in my medication, diet, exercise, etc. in my study diary; and
5) testing in the Bone Densitometry Research Laboratory (Building G02, Rm 2.08, Griffith University Gold Coast campus, Southport) on three occasions, which will involve the activities described in the information sheet;

- I have had any questions answered to my satisfaction;
- I understand the risks involved;
- I understand that the only known direct benefit to me from my participation in this research will involve free body composition scans, including analyses, and calcium and vitamin D testing;
- I understand that the information gained from this research may result in improved methods for diagnosis or treatment, but as an individual I do not have ownership of these results, research records, or the sample that I give;
- 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 explanation or penalty;
- I understand that I can contact the Manager, Research Ethics, at Griffith University Human Research Ethics Committee on 3735 4375 (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.

Please initial in the boxes if you also agree to the following:

☐ I agree to be photographed or filmed in the course of study-related activities to be used to demonstrate study procedures in reports of findings from the study.

☐ I agree for the investigators to access my medical records, including costs of health services and procedures during the 24 month course of the study.

Name	
Signature	
Date	