



UNIVERSITY OF  
BIRMINGHAM

College of Life and  
Environmental Sciences

School of Sport, Exercise and  
Rehabilitation Sciences

University Hospitals Birmingham   
NHS Foundation Trust

## THE INFLUENCE OF STRENGTH TRAINING AND VITAMIN D3 SUPPLEMENTATION ON MUSCLE AND BONE FUNCTION IN OLDER ADULTS

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### **Part 1**

#### **What is the purpose of the study?**

Muscle and bone loss are inevitable consequences of ageing, even if our health is good. We are looking at ways of reducing muscle and bone loss in

order to help improve the ability to perform tasks and activities important for independent living. The purpose of this research study is to find out whether a period of strength training combined with a vitamin D3 supplement is any more effective at improving muscle and bone function than strength training alone. In order to do this, we would like to measure the size of your muscles, along with their strength and power, do some tests to see how well you can perform tasks and activities important for daily living plus answer some questions about how you feel about your life just now. We would also like to take blood samples. We would like to see if any of these measurements change after strength training and whether taking vitamin D3 can help to boost these changes.

**Why have I been chosen?**

You have been chosen because you are 65 years of age or over and are living independently.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You will still be free to withdraw at any time in the future and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care that you receive.

**What will happen to me if I take part?**

If you are interested in taking part, we would like you to complete a brief screening health questionnaire. We will use your responses to the questionnaire to help determine whether you are eligible to take part in the

study. If you are eligible to participate, we will ask you to sign a consent form and then we will take a small sample of blood (just over a tablespoon full). We will also ask you to answer a few short questions about thinking and memory. The purpose of these procedures is to help us determine whether it is appropriate for you to continue with your participation. We will then ask you to wear a small monitor which measures physical activity for 7 days. After this we will then ask you to visit either your communal room or a facility close by (we will provide taxi transport if necessary) to take part in an exercise training study. This will involve getting together in a group with a specialist exercise instructor to do some strength and balance training exercises. This will take place 3 times a week for 6 months. You will also be asked to take either a vitamin D tablet or a placebo tablet once a day for 6 months. We will provide you with tablets 4 weeks at a time. Neither you nor we will know which type of tablet you are taking until the end of the study. Before and after the 6 months of exercise training combined with the tablets, we will ask you to come to the Wellcome Trust Clinical Research Facility at the Queen Elizabeth Hospital, Birmingham, in order to make some physical function measurements. We will provide taxi transport. At the end of the study you will be given a DVD to keep which will include the exercises you have been doing during the study. If something should happen whereby you do not fulfil the eligibility criteria any longer, then we would not continue with the collection of data but you may still participate in the exercise at the discretion of the study team's medical expert.

### **'What tests and procedures will be carried out as part of this study'**

Measurement of bone and body composition (DXA scan): This gives us information about your bone strength and body composition (that is, the amount of muscle, bone and fat in your body). The scan takes about 30

minutes and involves X-rays. However the radiation exposure you will receive by taking part in this study is equivalent to 4 days of naturally occurring background radiation which is an extra 1% of the annual naturally occurring background radiation. This additional risk is comparable to travelling 50 miles by car.

**Test of muscle power:** Your leg muscle power will be measured using specialised equipment and will involve simple pushing movements which you will be asked to hold for a few seconds. These tests will take about 10 minutes so you may feel a little tired afterwards but the tests should not cause any pain or discomfort. We will also measure the power you exert when you get out of a chair using a special force platform. This will take only a minute.

**Test of functional ability (short physical performance battery):** This is a short series of tests of balance, walking speed (over a few feet) and chair rise. It will take about 10 minutes.

**Test of functional ability (timed up-and-go):** This test will measure your ability to get up out of a chair and walk a few feet then turn around and go back to your chair. It will take 5 minutes.

**Questionnaires:** You will be asked to complete two questionnaires; one asks about your quality of life and the other about pain/ discomfort in muscles and bones. They will take approximately 20 minutes to complete.

**Measurement of physical activity:** We will measure this just before you do the other tests. We will attach a small physical activity monitor to your thigh

with sticky pads and ask you to wear it for 7 days. We would ask you to remove some of your clothing for a few minutes so that we can attach the monitor. The monitors are very small (1.5x2.5 inches) and lightweight (less than 1oz). You may bathe/ take a shower during this time (although if you wish to bathe we would ask you to remove the monitor while you are bathing). We will collect the monitor from you or provide you with a stamp-addressed envelope to return the monitor to us after 7 days.

**Food diary:** We will give you a special diary so that you can record the things you eat and drink over the course of 2 days (in other words 2 days at the beginning of the study and 2 days at the end).

**A blood test:** We will take small samples of blood from a vein (a total of four blood samples of 20ml which is just a bit more than a tablespoon). We will take a sample at the beginning (which we mentioned earlier), two during the study and one at the end. The samples will be used to check your vitamin D and calcium levels as well as other important chemicals in your blood.

**Measurement of blood pressure:** This test will allow us to measure your blood pressure whilst seated and also whilst standing.

### **What are the possible disadvantages and risks of taking part?**

We have taken every step in the design of this study to minimise any possible disadvantages and risks.

**What are the possible benefits of taking part?**

Regular exercise has many benefits not only in terms of improving muscle and bone function but also improving the ability to perform normal everyday tasks as well as helping to improve quality of life. We cannot guarantee that you will receive all of these benefits but we would be surprised if you didn't receive any. Taking vitamin D3 supplements may confer a small additional benefit. Even if you do not benefit directly from taking part in the study, the information we receive may help us to find ways of slowing down muscle and bone loss, not just in relatively healthy older people but in people with certain diseases characterized by muscle wasting.

**Part 2****What if relevant new information becomes available?**

If any clinically significant information comes to light as a consequence of taking part in this study, we will inform your GP (with your permission).

**What will happen if I don't want to carry on with the study?**

You can withdraw from the study at any time without having to give a reason. However, we may still choose (with your permission) to use any data obtained as a result of your participation. Any identifiable data will be anonymised.

**What if there is a problem?**

**Complaints:** If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do

this by contacting Dr Sean Jennings, Research Support Group, University of Birmingham (0121 415 8011 or [s.jennings@bham.ac.uk](mailto:s.jennings@bham.ac.uk) )

**Harm:** In the event that something does go wrong and you are harmed during the research study, the University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

**Will my taking part in this study be kept confidential?**

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. However, we would like to inform your GP of your involvement in this study but we will require your permission to do this. All other information about you which leaves the University of Birmingham will have your name, address and date of birth removed so that you cannot be recognised from it.

**What will happen to the results of the current research study?**

The results of this study will be published in medical journals, reports and textbooks. You will not be identifiable in any publication or report.

**Who is organising and funding the research?**

The research is being organised and sponsored by the University of Birmingham. The study is funded by the National Osteoporosis Society.

**Who has reviewed the study?**

This study has been given a favourable ethical opinion for conduct in the NHS by the Black Country Research Ethics Committee.

**Contact details**

You may contact me (one of the Principal Researchers) directly by telephoning 0121 414 8743 or email [c.a.greig@bham.ac.uk](mailto:c.a.greig@bham.ac.uk) for further information at any time. Alternatively, you may contact Dr Alison Rushton (School of Sport, Exercise and Rehabilitation Sciences) who is acting as an independent advisor. Her contact telephone number is 0121 415 8597 (email [a.b.rushton@bham.ac.uk](mailto:a.b.rushton@bham.ac.uk))

**Many thanks for taking the time to read this information.**

**Dr Carolyn Greig PhD**

**School of Sport Exercise and Rehabilitation Sciences**

**MRC-ARUK Centre for Musculoskeletal Ageing Research**

**The University of Birmingham**