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**School of Sport, Exercise and Health Sciences**

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**Effects of a Resistance Exercise Programme on Risk of Osteoporosis and Osteoarthritis in Females (REPROOF)**

**Participant Information Sheet**

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# **Invitation and brief summary**

We would like to invite you to take part in our study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please read the key information on pages 2-6. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study before making a decision if you wish.

This study will examine the effects of resistance training on bone, joint and muscle health in postmenopausal women. This will help us to understand what types of exercise may be best for preventing osteoporosis (brittle bones) and osteoarthritis (painful joints).



# **KEY INFORMATION**

## **Who is needed for the study?**

We are looking for **healthy women aged 50 to 70**, who are at least five years since menopause (or last using hormonal contraception or hormone replacement therapy).

We may not be able to include you if you: have injuries or medical conditions affecting exercise; take medication affecting bone; already do substantial exercise involving weights or impact; have high blood pressure; have BMI > 30 kg/m2; have some types of metal implants not suitable for MRI or have had a fracture within the past year.

**What will I be asked to do?**

You will be asked to come to the university for measurements at the beginning, middle and end of the eight-month study. We will ask most volunteers to take up exercise, whilst some carry on as normal as a control group. Exercisers will be asked to come to exercise classes twice a week during the study.

##

## **Study outline**



## **Measurements**

The measurements taken at the beginning, middle and end of the study will include:

* **Questionnaires** about your background, medical history, physical activity level, pain, calcium intake and any metal that may affect MRI scans.
* **Dual Energy X-ray absorptiometry (DXA) scan** to measure bone density (Figure 1). Femur, spine, forearm and whole-body bone density will be measured. This will give information us about your current bone health and risk of osteoporotic fracture.
* **Peripheral Quantitative Computed Tomography (pQCT) scan** to measure the 3D structure of the bone in the forearm and lower leg (Figure 2).
* **MRI scan** of the knee joint and thigh muscles (Figure 3). This will assess the quality of the cartilage in the knee, which has been linked to risk of future osteoarthritis, and the size of the thigh muscles. This measurement will be done at the beginning and end of the study only.
* **Blood and urine sample** to examine changes in the metabolism of bone and cartilage. One small tube (approximately one tablespoon) will be taken from a vein in your arm and you will be asked to collect a small sample of urine in a container that we will provide.
* **Muscle function measurements:** Maximal muscle strength will be assessed with two exercises: the hack squat (Figure 4) and calf raises. In addition, we will measure how quickly you can move a range of weights ranging from light to heavier.
* Some simple **tests of physical function**, e.g., how quickly you walk a 4-metre distance and balance (e.g. how still you can stand).



Figure 1: Figure 2:

DXA scan pQCT scan



****Figure 3: Figure 4:

MRI scan Hack squat machine

## **Study Groups**

After the measurements are complete, participants will be divided into three groups: two exercise groups, one control group (usual life group). Allocation will be randomly decided, and you will not be allowed to choose a group to attend.

### **Control Group**

If you are in the control group, you will continue your everyday life. Please try not to change your usual exercise or diet during the study.

### **Exercise Groups**

If you are in one of the exercise groups, you will be asked to visit NCSEM **twice a week for 30 weeks**. We will offer a range of times and days to try and find a convenient time for you. You will be exercising with a small group of other women from the study.

The exercises are designed to strengthen major muscle groups of the trunk and lower body, as well as to load bones that are affected by osteoporosis and the knee and hip joints that are commonly affected by osteoarthritis. Each exercise training session will take **30-40 minutes** and will be done using resistance (hack squat) machine in a dedicated exercise facility. We chose a hack squat machine as it exercises many muscle groups and bones in one exercise. Additionally, it supports your spine, making it safe to use. You will start off using light weights and these will increase as you become stronger. Muscle strength and physical function measurements will be repeated periodically during training sessions, to monitor your progress.

The two exercise groups will follow the same exercise programmes but using different speeds and weights. The conventional training group will perform the exercises slowly, whilst the ballistic group will use a lighter weight and more rapid movement, as if trying to jump. You will be carefully guided and coached to perform all the exercises correctly and all the exercise training sessions will be supervised by qualified researchers to ensure your safety throughout the study.

## **Study sessions**

You will be invited to **eight measurement sessions**: three at the beginning, two at the16th week, and three at the end of the trial (32nd week). Each visit may last **up to two hours**. Sessions will be arranged at a mutually convenient time as far as possible, although the availability of the MRI scanner is more limited so we can be less flexible with this appointment.

If you are in an exercise group you will also be asked to attend **exercise sessions twice a week for 30 weeks**. Each visit will take approximately **one hour** including ~30-40 minutes of exercise, warm up and rest breaks.

All visits for both groups will be at the National Centre for Sport and Exercise Medicine (NCSEM) clinical facilities and/or research lab.

We will make a payment of £3 per visit to cover any **travel costs**. This may amount to a maximum of £204 for people in exercise groups, or £24 for people in the control group who will make fewer visits. These expenses will be paid bi-monthly.

## **What should I do, bring or wear before the sessions?**

Please keep a **food diary** and eat a normal breakfast before the visits that include a blood sample. Please eat exactly the same food and drink before the next blood sample visits.

Please bring any **medication** needed during the visit.

For all **exercise and testing sessions**, please wear loose-fitting/stretchy clothes and trainers or similar footwear to allow you to move freely and perform weight machine exercises. A T-shirt with joggers, leggings or shorts may be ideal. If you prefer, you can bring your own water bottle, towel, and food for the exercise sessions.

Please make sure that there are no **metallic objects** in your clothing for the DXA, pQCT and MRI visits, e.g., zips, buttons, wiring or hooks in bras. It is also very important to remove all metallic objects before entering the scanner e.g., watches, jewellery (such as earrings and necklaces), piercings (such as ear and nose rings), dentures, hearing aids and wigs (some wigs contain traces of metal).

We have toilet and changing facilities available.

## **Possible benefits of participating**

If you are in an **exercise group**, you will have seven months of individualised exercise training, with other similar people. You may notice some benefits of exercise, including becoming stronger and more toned, having better posture etc. Resistance exercise is known to have a number of other health benefits, including increasing bone density, reducing risk of cardiovascular disease, diabetes, improving mental health etc. Although we cannot be sure whether you would have these benefits from taking part in the study, participants in previous studies found it a positive experience. We will also offer advice on strengthening pelvic floor muscles if relevant. These exercise sessions and exercise programmes will increase your knowledge about how to perform the resistance exercise. Furthermore, hopefully, you will gain exercise habits and increase your quality of life with greater knowledge and experience.

If you are in a **control group**, you will be prescribed a training plan at the end of the research.

All participants will receive information on the results of the different measurements.

Finally, but perhaps most importantly, you will be a part of research to increase our knowledge for on what types of exercise may reduce risk of osteoporosis or osteoarthritis.

## **Possible disadvantages or risks in participating**

You will have three instances of **X-ray imaging** of your body, called DXA scanning and pQCT, to estimate bone density and structure. Exposure to x-rays brings a small risk of causing cancer years in the future. In this trial you will receive x-ray (radiation) exposure that you wouldn't have otherwise had, and this amounts to the equivalent of around two months of UK background radiation. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage in life. Taking part in this study will add only a very small chance of this happening to you.

*MRI scans* are considered a safe procedure, but you need to stay still for some time and the scanner makes noises during measurement. Some people dislike the noise of being in the MRI scanner but you will be given ear defenders and could listen to music. The scan should take no more than an hour.

*Injury during exercise:* Due to the physical nature of the activity being performed, there is a potential risk of injury (e.g. pulled muscle) whilst performing resistance exercises or tests. Sessions will be supervised, you will warm up before each session and we will make sure that you know how to exercise correctly. To minimise risks, we will follow recommendations of the American Heart Association and American College of Sports Medicine. All sessions will be supervised by at least two investigators, at least one of whom will be a trained first responder.

*Blood samples:* Risks of collecting blood samples include bruising or feeling faint. The researchers are phlebotomy trained and have regular experience with blood collection. We will have a couch that you can lie on to reduce faintness.

*Transmission of pathogens (Covid-19):* We will follow all government and university advice, erring on the side of caution. The research will take place in a large, well-ventilated room and with a small number of participants for each session. We will ask all participants and researchers to confirm that they have no symptoms prior to attending. Researchers are vaccinated. All equipment will be cleaned between each participant. We will ask you and other participants to clean your hands using soap and hot water or hand sanitiser on arrival and departure.

*Incidental Findings from scans:* If we find that you may have low bone density or notice any other relevant findings based on your baseline scans, we will send the results to your GP so that you can seek their advice.

## **Once I take part, can I change my mind?**

After you have read this information and asked any questions you may have if you are happy to participate, we will ask you to complete an Informed Consent Form. However, if at any time, before, during or after the sessions you wish to withdraw from the study, please just contact one of the main investigators (Ogulcan Caliskan or Dr Elisa Marques). You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing.

However, once the results of the study aggregated (31 September 2023) it may not be possible to withdraw your individual data from the research.

## **I have some more questions; who should I contact?**

Ogulcan Caliskan, PhD Researcher, o.caliskan@lboro.ac.uk

Dr Elisa Marques, postdoctoral researcher, e.marques@lboro.ac.uk

Dr Katherine Brooke-Wavell, Senior Lecturer. K.S.F.Brooke-wavell@lboro.ac.uk, 01509 222749

# **FURTHER SUPPORTING INFORMATION**

## **Who is doing this research and why?**

This study is part of a research project supported by Loughborough University and the Versus Arthritis Centre for Sport, Exercise and Osteoarthritis. It will be carried out by:

* Ogulcan Caliskan, (PhD research student), Loughborough University
* Dr Elisa Marques (Research Associate), Loughborough University
* Dr Katherine Brooke-Wavell (Senior Lecturer in Human Biology), Loughborough University
* Professor Jonathan Folland (Professor of Neuromuscular Performance), Loughborough University,
* Dr Winston Rennie, (Consultant Musculoskeletal Radiologist), University Hospitals Leicester NHS Trust.
* Researchers may be assisted by MSc students Natasha Kirk, Chloe Peters, Ellie Scott and Nico Schwandt.

The project has been reviewed by West Midlands- Solihull Research Ethics Committee.

## **Data protection and privacy**

Loughborough University will be using information/data from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

**What personal information will be collected from me and how will it be used?**

We will ask for your name, date of birth, contact information, and medical history. In addition, -we will take measurements of body weight and height, blood pressure, bone mineral content, body composition, knee joint structure and will analyse your blood and urine.

All data will be anonymised and stored securely in a database that could be accessed for this study and for use in future research on related topics. These will be stored separately from health information such as blood samples and bone mineral density.

**What is the legal basis for processing my personal information?**

The data will be used to describe the characteristics of people taking part in research as a group. Individual results will not be reported in any conference, publication or thesis. Personal data will be processed on the public task basis. For further details on the data protection legislation see: <https://ico.org.uk/your-data-matters/>

Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as “sensitive data”. The processing of this data is necessary for scientific research in accordance with safeguards. This means that study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data.

**How long will my personal information be retained?**

We will keep identifiable personal information about you until the end of the study (31/12/2025).

**Will my personal information be shared with others?**

Anonymised data will be shared with all investigators taking part in the study.

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

Yes. As soon as you take part in the study, you will be assigned a study code (such as RT01). This code will have no reference to your name or any other personal details and will be stored securely in a file only accessible to the direct research team. All data and samples will be identified only by this code. Data will be stored in locked filing cabinets and/or university’s cloud-based secure system. Information linking participants names and study numbers will be stored securely in a separate location.

**How will the anonymised data/results collected from me be used?**

Data collected will be used as part of a research project at Loughborough University. Then, the results of the study will be published in scientific journals and presented at relevant scientific and medical conferences. We will share results with you and be happy to explain our findings.

The scans are not general health scans, and any other issues you are experiencing should be reported to your GP as normal. The DXA measurements may detect low bone density, in which case we will inform your GP. The MRI images obtained are solely for the purpose of the study and not for clinical diagnosis. There may be a rare occasion where MRI scans reveal an unexpected finding which may or may not have health implications. On these rare occasions, your scan may be reviewed by a radiologist, and any recommendations passed to your GP.

**How long will the anonymised data and samples be retained?**

We will keep anonymised data, scans and samples until 31/12/2034.

## **What if I am not happy with how the research was conducted?**

If you are not happy with how the research was conducted, please contact the Secretary of the Ethics Review Sub-Committee, Research & Enterprise Office, Hazlerigg Building, Loughborough University, Epinal Way, Loughborough, LE11 3TU. Tel: 01509 222423. Email: researchpolicy@lboro.ac.uk

The University also has policies relating to Research Misconduct and Whistle Blowing which are available online at <https://www.lboro.ac.uk/internal/research-ethics-integrity/research-integrity/>.

If you require any further information regarding the General Data Protection Regulations, please see: <https://www.lboro.ac.uk/privacy/research-privacy/>.