Participant Information Sheet

Study Title: The chronic effects of eccentric exercise on neuromuscular characteristics in older people.

(The long term effects of a specific training programme on the neurological and muscular system in older adults).

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have during a pre-meeting. This should not take more than 10 minutes. Part 1 of this Participant Information Sheet tells you why we are doing this research and what will happen to you if you take part. Part 2 gives you more details about how the study will be conducted.

Background to this research

The purpose of this study is to examine the training adaptations in response to 12 weeks of training, detraining and retraining examining muscular adaptations and physical function.

PART 1 OF THE INFORMATION SHEET

How have I been selected?

You have been invited to take part in this study because you fit the inclusion criteria and have indicated that you are happy for us to invite you to join the study.

Do I have to take part?

No, it is your choice whether or not to take part. Please talk to others about the study if you wish, and ask me if anything is not clear. If you decide to take part, you can leave the study at any time without giving a reason.

What will happen to me if I take part?

When you are recruited you will be shown the equipment that will be used during your participation. You will be able to ask any questions that you may have at this point before deciding you are interested in taking part.

What will I have to do?

If you decide to join the study, you will be asked to attend two initial sessions to try and practice the equipment being used. Following these sessions, you will be required to complete a questionnaire reporting your quality of life and then you will undergo a 12-week training programme using specialised exercise equipment (similar to a laying back exercise bike, see image below), which will require you to push against pedals using each foot alternately, this will be demonstrated in the practice session before the training programme starts. Outside of the training sessions you will be required to wear an activity tracker all day except washing and sleeping.

After 12 weeks of training you will be required to undergo 12 weeks of detraining, this will require you to stop the training programme and continue with daily living as normal for 12 weeks. You will be asked to come in following 6 and 12 weeks of this detraining period. Activity levels will be monitored using an activity monitor through the detraining period. **It should be noted that any improvements that may have occurred as a result of the training period may regress back to levels before you began the training.**

Following the 12 weeks of detraining you will then take part in a retraining programme that will last 12 weeks. This will require you to carry out the original training intervention that you carried out for the initial 12 weeks. An activity monitor will be required to be worn in your daily living and data will be collected following 6 and 12 weeks. **In total you will be required to commit to 37 weeks, 12 of these weeks will not require training and 24 will require training.**

Practice Session (45 – 60 minutes)

When you arrive at the laboratory I (the lead researcher) will explain what the session and subsequent sessions will involve. You will be required to sign an informed consent form and a medical questionnaire to say you are happy to be a part of the study and do not have any medical issues that restrict your participation. You will be required to watch a demonstration of the tests from me for each test and then perform practice tests yourself with opportunities to ask any questions you have about the procedure.

Muscle strength
Muscle strength will be measured using a strength testing machine, this will require you to be seated in an upright position and safely strapped into the chair with your knees bent. You will attempt to push against the unmovable bar in front of your shins as hard as you can after a series of warm-up and practice attempts.

Muscle structure
Muscle structure will be measured using ultrasound imaging which will require you to sit upright, images will be taken of your right thigh and will therefore require any item of clothing to be pulled up above your mid-thigh and contact will be made from me with the ultrasound scanner to capture the image. Before I capture the image I will mark a halfway point between your hip and knee with a marker pen; I will also measure the length of your thigh and leg from your hip with a tape measure.

Physical function

To measure physical function, you will undergo 3 tests that are mentioned below.

Sit-to-stand test
The sit-to-stand test will require you to stand from a chair with no arm rests or support to a standing position and then back to a seated position ten times. I will countdown (3-2-1-GO) and the time taken to perform these ten stands will be recorded. This will be repeated twice with a minute rest between.

Timed get up and go
The timed up and go test will require you to start seated in an armless chair. When I countdown (3-2-1-GO) you will be required to get up out of the chair, walk 3 metres, turn around and sit back down in the chair independently, you will have to do this 3 times with a minute rest between.

Functional Reach
The functional reach test will require you to stand upright and lean forward with your arm outright in front of you with a clenched fist next to a metre stick. The distance of your fist along the metre stick will then be measured, this will be done 3 times.

Activity levels
Throughout the study you will be provided with a Fitbit activity monitor which will be used to examine your daily step count, it is advised that you wear this device as much as possible, the monitor will be clipped onto your waist.

Quality of life, rate of perceived exertion, muscle soreness and number of falls
You will be required to fill out a questionnaire before undertaking any training or testing regarding your quality of life and well-being. After the training sessions you will be asked to rate how hard the session was and how sore your muscles are immediately after the training, muscle soreness will be tested by myself pressing against your thigh muscles and you rating the soreness on a scale of 1-10. After the study you will be contacted via telephone every three months for one year to ask if you have fallen and how many falls you have had if this is the case.

How will we contact you about visits?
We will ask you your preferred method of communication including telephone call, text messaging or e-mail to remind you about your visits.

Will I be paid for my participation?
You will not be paid for taking part in this study.

Why might you be not able to take part in the study?
If you have a history of heart disease (including irregular heartbeats), respiratory disease, high blood pressure it is advised you consult with your practitioner prior to taking part; if you have a condition and/or are taking medicine that alters neuromuscular system and/or balance you will not be able to participate. If you require assistive walking devices such as crutches or a walking stick and/or have been advised by your practitioner to avoid high demand exercise you will not be able to take part in this study.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2 of this sheet.

Will my taking part in the study be kept confidential?
I will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you may want to join the study, please read the additional information in Part 2 before making any decision.

PART 2 OF THE INFORMATION SHEET

What if relevant new information becomes available?
If additional information becomes available during the course of the research, it will mainly be conveyed in the form of e-mail or by letters if you have no access to e-mail (through internal post).

What will happen if I don't want to carry on with the study?
If you decide to take part, you can still leave the study at any time without giving a reason. Identifiable data already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to you.

Who is organising and funding the research?
The University of Northampton is organising this study. I, the lead researcher, the lab technician and any other researchers that may provide assistance throughout the study are staff or students of the University of Northampton or are employed by University.

What if there is a problem or you are unhappy with the conduct of this study?
If you have any concerns or issues with the study please speak to Prof. Tony Kay (email – tony.kay@northampton.ac.uk) in the first instance, unless you feel it more appropriate to speak to the Dean of the Department of Health & Society (email – steve.o'brien@northampton.ac.uk).

All research is looked at by independent groups of people, called a Research Ethics Committee, to protect your interests.

If you do decide to take part, you will be given a copy of this information sheet to keep, and will be asked to sign a consent form.

Will my taking part in this study be kept confidential?
If you decide to take part in this study, any information collected about you as part of this project will remain confidential and your identity will not be revealed. Any information about you which is collected will have your name and address removed so that you cannot be recognised. Data will be handled, processed and stored in accordance with the Data Protection Act 1998 http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1

What will happen to the results of this study?
Any information collected about you will only be used for the purposes of this project and will be disposed of securely when research is complete. The results may be published in scientific journals, undergraduate/postgraduate reports and used in presentations to healthcare and other interested parties. You will not be personally identified in any report or publication. You can request a copy of the findings. This is **NOT** a clinical diagnosis and you will **NOT** be able to request this data to be withdrawn after it has been collected.

For further information about this project please contact

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Thank you for taking time to read this Participant Information Sheet.