PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Plain Language Statement

Full Project Title: Non-invasive estimation of intrinsic motor neurone excitability in sarcopenic individuals and masters athletes: the "neuropenia" study
Principal investigator: Dr Lucas Orssatto
Research team: Prof Robin Daly and A/Prof David Scott

This Plain Language Statement and Consent Form is 7 pages long. Please make sure you have all the pages.

1. Your Consent

You are being invited to take part in this research project as you are aged 65 years or over. This research will investigate the differences in motor neurone properties (the nerve connecting your brain to the muscles) among older people with sarcopenia, those without sarcopenia, and Masters athletes. This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read the Plain Language Statement carefully. Feel free to ask any questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker or doctor. Feel free to do this. Once you understand what the project is about and if you agree to take part in it, we will ask you to provide your consent online. By signing the Consent Form, you indicate that you understand the information you have read, consent to take part in the study, consent to have the tests and treatments that are described, and consent to the use of your personal and health information as described. You will be given a copy of the Plain Language Statement and Consent Form to keep as a record.

Participation in this study is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether or not to participate will not affect your relationship with Deakin University.

2. Purpose and Background

Older adults experience a gradual reduction in muscle mass, strength and function as part of the ageing process. When these losses in mass, strength and function are accelerated, this is collectively termed sarcopenia and may be linked with several chronic diseases. Dysfunction in the nerves that connect our brain to our muscles contribute to the reduced strength and physical function observed during ageing. However, we do not know if individuals with exacerbated physical function and strength losses (i.e., sarcopenic) present further impairments in motor neurone properties. Also, we do not know if Masters athletes have some preservation in the age-related impairments in motor neurone properties.

You are invited to participate in this study because you:

- Are 65 years of age or over.
- Are not practicing progressive resistance training or challenging balance/mobility training (>1/week) in last 6 months (except for Masters athletes).
- Do not have lower limbs orthopaedic conditions (e.g., injuries) preventing the performance of lower body movement and tasks.
- Are not currently undertaking medications affecting the serotonergic and/or noradrenergic systems (e.g., Selective serotonin reuptake inhibitors (SSRIs) and beta-blockers).
- Did not received recent (last 6 months) medication treatment influencing muscle mass and strength (e.g., cancer-related chemotherapy, hormone replacement therapy and anabolic steroids),
- Are able to speak or read English.
- Do not report any cognitive impairments

This study is funded by Deakin University and Institute for Physical Activity and Nutrition (IPAN). There are no costs to you associated with participating in this research project, nor will you be paid but you will be provided with parking fee or bus tickets reimbursement.

3. Procedures – what you will be asked to do

If you decide to participate in this study, we will be asking you about some of your medical history in an initial telephone screening test in order for you to participate safely in this study. To participate in this study, you must pass the initial telephone screening test conducted by one of the research staff, and sign this Participant Information and Consent Form. Upon entry into the study, you will be screened for sarcopenia or athletic history and allocated to the respective group (sarcopenic, non-sarcopenic, or Masters athlete).

Study Measures

We will collect health, medical and lifestyle related information from you and ask you to complete a number of questionnaires, self-reported measures and physical assessments. We will be performing these measurements in a single session (duration ~3 hours), including:

1) Your body weight and height will be measured using a scale and stadiometer. Your body composition (amount of muscle and fat) will be measure with bioelectrical impedance, which is a non-invasive device,
2) Your physical function will be measured with the 5-times sit to stand, timed-up-and-go, and walking speed tests. These tests mimic daily living activities, such as sit to stand and walking tasks. You will also answer to questionnaires of self-reported physical activity, physical function, and disabilities.
3) Your arms and legs strength will be measured with specialised device. You will be asked to perform maximal and submaximal brief static contraction using your handgrip and lower leg strength. The maximal contractions should last around 5 seconds and submaximal around 20 s. A skin electrode matrix will be placed on your lower leg muscle (over the skin) during the assessments to record muscle activity.

4. Possible Benefits

We cannot guarantee or promise that you will receive any benefits from this project. We expect that the findings from this study will make an important contribution to the development of targeted and effective interventions (e.g., nutritional and exercise) to improve muscular strength and physical function in older adults with or without sarcopenia in the future.

5. Possible Risks

Possible risks, side effects and discomforts related to this study include the following:

The physical assessments will involve muscle contractions, and you may experience some minor and transient muscle soreness during and following the sessions. However, the assessments have been shown to be safe and acceptable for older and frail populations (e.g., motor neurone disease, spinal cord injured, and multiple sclerosis patients). Precautions have been taken to minimise the risk of physical injury to you, but as with all types of exercise there are some risks involved, such as muscle strain. You will be given advice on how to avoid this from occurring and how to recognise if there might be a problem. It is important that you report any pain or discomfort so we can monitor your progress/safety.

The sticky gel electrode placed on your leg muscle during the physical assessment cause a slight allergic reaction (rash). However, this should be transient, and the sites will be correctly prepared before placing the electrodes, which should minimise this risk.

You may experience distress when receiving the tests results, if your results are lower than you expect. However, you will receive advice from the research team and health professionals of potential strategies to mitigate this potential issue.

There may be additional unforeseen or unknown risks that the researchers do not expect or do not know about. Please tell the research team and your doctor immediately about any new or unusual symptoms that you get.

There will be continual review and monitoring during your participation in this research study to enable the early detection of any problems that you may experience. You will be allowed to video/email/text our research team, and we will be able to assist you with any questions and issues, related with the study, you might have before and after participation.

6. What are the alternatives to participation?

You do not have to take part in this research project. Other options are available for improving your health including following your GP, dietitian, and health providers' advice. You can discuss this with your doctor/GP before you decide to take part in this research project.

7. Other Treatments Whilst on Study

It is important to tell the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins, or herbal remedies during your participation in the study.

8. Privacy, Confidentiality and Disclosure of Information

Any personal information provided by you to the researchers involved with this project will remain confidential. It will only be disclosed with your permission, subject to legal requirements.

All collected information will be labelled with a unique study code, and not with your name or any other identifying information, which will be kept separate from the information collected. All data will be kept in a database stored on a computer which will be password-protected and only accessible to the research staff involved in this study and may be used in future research which is closely related to this project. In the future, we may also wish to share some non-identifiable aggregate research data with other groups that obtain relevant ethics approval that are not immediately involved in this project, but your information will remain non-identifiable. Your name will NOT be used in any published report, presentation or output. In accordance with the *Freedom of Information Act* 1982 (Vic), you have the right to access and to request correction of information held about you by Deakin University.

9. New Information Arising During the Project

Although unlikely, during the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research.

Similarly, as you will be monitored during the testing session, if it appears for any reason that you or the research staff are at risk by your continuing participation in the testing session, the person(s) supervising the research will stop your participation. In all cases you will be offered all available care to suit your needs and medical condition.

10. Results of Project

Upon completion of the project, it is anticipated that the results will be submitted for potential peer-review and journal publication in the field of neurophysiology and ageing. The results may also be presented orally to a scientific meeting in Australia or internationally. Upon completion of the study, all participants may request to receive (via post or email) the main findings from the study and a copy (booklet) of their key results. Annual reports will be provided to Deakin University Human Ethics Research Committee.

11. Further Information or Any Problems

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the principal researcher or student researcher.

Contact Person	**Telephone Number**
Dr Lucas Orssatto	03 9244 5839
Professor Robin Daly	03 9244 6040

12. Complications

If you suffer any complications as result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment.

13. Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact: Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au. Please quote project approval number [2023-241].

14. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage before data collection or within 15 days after your participation.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with Deakin University. If you choose to withdraw, you will also have the option to request to withdraw your data from the research project if you wish to do so.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Electronically sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team or complete and return the Withdrawal of Consent Form attached. This notice will allow the research team to inform you if there are any health risks or special requirements linked to withdrawing.

15. Ethical Guidelines

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Deakin University Human Research Ethics Committee (EC 2023-241).

16. Funding source and amount

This research project is funded by an Alfred Deakin Postdoctoral Research Fellowship provided to Dr Lucas Orssatto, with a research budget of $15,000.

16. Termination of the Study

This research project may be stopped for a variety of reasons. These may include reasons such as unacceptable side effects.

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Consent Form

Full Project Title: Non-invasive estimation of intrinsic motor neurone excitability in sarcopenic individuals and masters athletes: the “neuropenia” study

Reference Number: [2023-241]

I have read, and I understand the attached Plain Language Statement.

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.

Please do not sign this form before your first testing appointment at Deakin University with a member of the Deakin research team.

□ I would like to receive a report with my personal results of the study.

Participant’s Name (printed): …….....

Signature: ……..……...

Date: ……..……

PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Withdrawal of Consent Form

Full Project Title: Non-invasive estimation of intrinsic motor neurone excitability in sarcopenic individuals and masters athletes: the “neuropenia” study

Reference Number: [2023-241]

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardize my relationship with Deakin University.

□ Please destroy any personal information and data obtained from my participation in the study.

Participant’s Name (printed) ……..……..…….

Signature ……. Date ……..……..……

Please mail this form to:
lucas.orssatto@deakin.edu.au
School of Exercise and Nutrition Sciences
Deakin University
221 Burwood Highway
Burwood, Victoria 3125