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Participant Information and Consent Form

Sarcopenia Trial: Resistance training and Oral Nutrition in the Aging (STRONG Trial)

Invitation

You are invited to participate in a research study examining whether a strength exercise program delivered by a physiotherapist in combination with improved nutrition can improve muscle mass, strength or muscle function in an older population. This study is being carried out by Professor Lisa Wood from the Hunter Medical Research Institute (HMRI) and the University of Newcastle. Data from this study will form part requirement for a PhD at the University of Newcastle by Isobel Stoodley. This study is sponsored by an industry partner (NSA, LLC). NSA LLC have signed a contract with the University of Newcastle to fund this study. The researchers will receive no direct payment from the sponsor for conducting this study.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

Healthy adults lose muscle tissue after the age of 65, due to the normal ageing process. Unfortunately, the loss of muscle mass is related to increased frailty and higher rates of falls, hospital admissions, reduced quality of life and loss of independence. Some research studies have shown that doing regular strength (resistance) based exercises and improving nutritional intake can help to rebuild muscle strength and improve daily functioning. We will investigate whether performing strength exercises at home 4 days per week and consuming a drink twice daily for 16 weeks can improve muscle size, strength and function in older adults.

2. 'Why have I been invited to participate in this study?'

You may have received this invitation if you are part of the HMRI Research Volunteer Register or the Respiratory and Sleep Medicine Outpatient Database and have agreed to be contacted for research studies. This study may be suitable for you if you are aged 65 years or older. If you are a current smoker, or undertaking regular moderate intensity exercise training (>150 minutes a week), or taking insulin, or have a thyroid condition, or are unable to drink cow's milk, or are allergic or intolerant to soy or have a body mass index (BMI) ≥40kg/m2, then this study may not be suitable for you.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you decide to withdraw from the study, you have the option of withdrawing all data relating to you and have any blood samples that have been taken destroyed. An exception to this is in the case of an adverse event, or a serious adverse event, where the data needs to be retained for regulatory reporting.
The researchers may withdraw a participant if it is considered in the participant's best interest or it is appropriate to do so for another reason. If this happens, the researchers will explain why and advise you about any follow-up procedures or alternative arrangements as appropriate.

4. 'What does this study involve?'

If you agree to participate in this study you will be asked to:

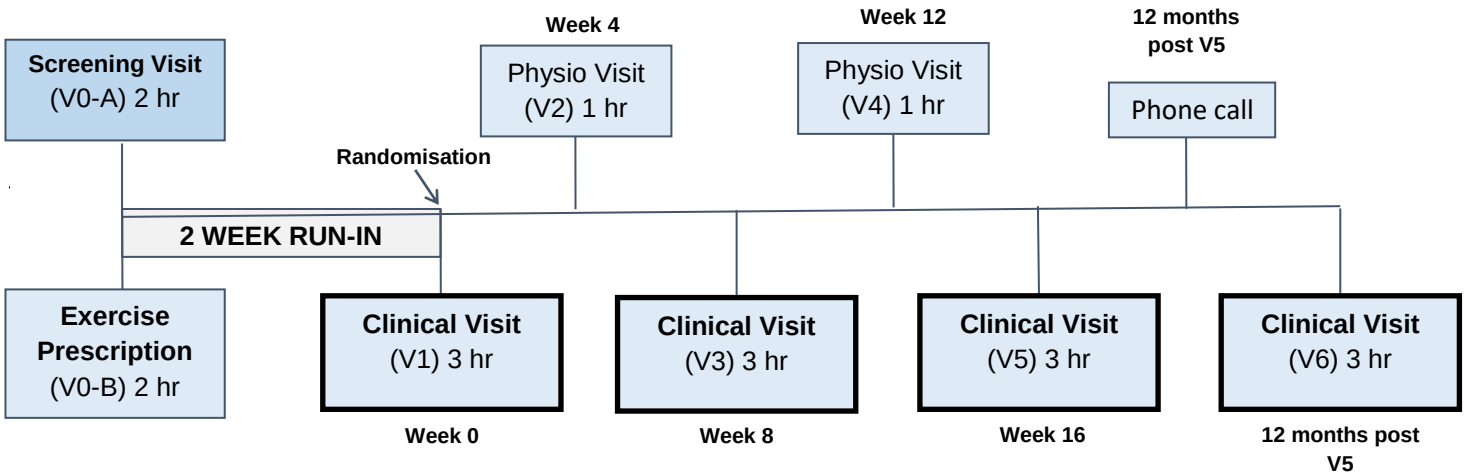
- Sign the Participant Consent Form.
- Attend the HMRI clinic to undergo a screening visit, then if the study is suitable for you, attend another visit to have a strength exercise program tailored to your needs. This will include upper and lower limb strength training using hand-held weights 4 days per week.
- Perform the home exercise program and consume 250mL skim milk twice daily for 2 weeks as a 'run-in' period. This run-in period will allow you to see whether this study is suitable for you.
- After 2 weeks, if you choose to participate, you will continue the strength exercise program at home and start consuming a study drink, twice daily. This will either be:

  Group 1) 1 cup (250ml) skim milk + nutritional supplement powder twice daily or

  Group 2) 1 cup (250ml) skim milk twice daily

  Whether you are allocated to Group 1 or 2 will be randomly decided (like tossing a coin). You will have an equal chance of allocation to each group but we cannot place you in the group of your choice.
- Attend clinic visits at HMRI (details to follow) every 4 weeks for 16 weeks, during which you will be required to consume one of the study drinks twice each day and perform strength exercise training at home 4 days per week.
- This study takes 18 weeks to complete and involves <u>seven</u> visits to the Hunter Medical Research Institute.
- 12 months following your completion of the study, you will be invited to attend a follow-up visit at HMRI.

<u>Study Visit Schedule</u>



Screening Visit:
This visit is to check that the study is suitable for you, it will take approximately 1 hour and will include:

- A brief medical examination including measurement of your height, weight, blood pressure and an electrocardiogram (ECG). The ECG will involve placing stickers on your chest, arms and legs while you are lying on a bed. This will allow us to obtain a graph of your heartbeat and rhythm. The test is painless and takes about 15 minutes;
- Questionnaires about your medical history, cognitive state, smoking history, dietary intake, food allergies and intolerances, weight history and medication usage;
- A blood test to measure your blood chemistry (full blood count, liver function test, electrolytes, urea, creatinine). This blood test will require approximately 8mL of blood (1.5 teaspoons).

If our screening assessments indicate that the study is suitable for you, after this visit we will send a letter to your GP with information explaining the study, your blood test and ECG results and an exercise clearance form which must be signed off by the GP, clearing you to participate in the strength exercise program. If you choose to participate, we will organise a mutually convenient time for you to attend the clinic to have an exercise programme tailored to your needs and explained to you.

If this study is not suitable for you, with your permission we will advise your GP of your test results and will forward the information to your GP for follow up.

Exercise Prescription Visit:
Two weeks prior to the start of the study we will invite you to attend the research clinic at HMRI for approximately 1.5 hrs. At this visit the study physiotherapist will develop your individualised home-based strength exercise program. We will ask you to complete questionnaires on your physical activity levels and your diet and your body composition will be measured using bioelectrical impedance analysis (BIA) (see below for a description of this process).

2 Week Run-in Period:
We would like you to start doing the strength exercise program and drink 250ml of skim milk twice daily for 2 weeks. This run-in period is to help ensure that you will be able to manage doing the strength exercises 4 times a week. If you are happy to continue the exercise program we will organise a mutually convenient time for you to come in for the baseline assessment visit (Visit 1).

Study Drink
The nutritional supplement powder used in this trial is a formulated supplementary food, which means that it is a supplement to a normal diet. It will be provided to subjects in one group only, in single serve sachets, to be mixed with 250ml of milk and consumed twice each day. It contains nutrients that are normally found in the diet. There are no known adverse effects when used as described. However it does contain soy and is therefore not suitable for those with allergies or intolerances to soy.

Study Diary
You will be supplied with a study diary, to record when you complete your exercise sessions, have your study drink and if you experience any unusual symptoms. This will take about 1 minute of your time each day.

Tests during the study visits:

Visit 1 – 3hrs	Visit 2 – 1hr	Visit 3 – 3hrs	Visit 4 – 1hr	Visit 5 – 2.5-3hrs	Visit 6 – 2.5-3hrs
-Fasting blood test ~34mL (1.5 tbsp)	-BIA scan	-Fasting blood test ~31ml (1.5 tbsp)	-BIA scan	-Fasting blood test ~34mL (1.5 tbsp)	-Fasting blood test ~34mL (1.5 tbsp)
-Body weight	-Exercise assessment	-Body weight	-Exercise assessment	-Body weight	-Body weight
-BIA scan		-BIA scan		-BIA scan	-BIA scan
-DXA Scan		-DXA Scan		-DXA Scan	-DXA Scan
-Blood pressure		-Blood pressure		-Blood pressure	-Blood pressure
-Physical Performance & Strength tests		-Physical Performance & Strength tests		-Physical Performance & Strength tests	-Physical Performance & Strength tests
-Questionnaires		-Questionnaires		-Questionnaires	-Questionnaires
-Exercise assessment		-Exercise assessment			

Description of tests:

- **Blood Test -** Blood will be collected from a vein in your forearm to measure your blood chemistry and markers of muscle growth and dietary nutrient levels. Before you attend these visits we would like you to fast for 12 hours, however you may drink plain water during this time. Blood will be collected on arrival. You may have something to eat after the body composition scans (~1 hr) and we will have snacks available.
- **Bioelectrical impedance analysis (BIA Scan) -** Bioelectrical impedance analysis (BIA) is a simple and safe measure of body composition. This will allow us to monitor changes in your muscle mass, body water and fat mass throughout the study. It is as simple as standing on a set of scales for approximately 90 seconds.
- **Body Composition & Bone Mineral Density (DXA Scan) -** We will measure your body composition and bone density using a dual energy x-ray absorptiometry (DXA) machine. This is a routine procedure that involves the use of very low levels of radiation. You will be asked to lie on a bed underneath a scanning arm that emits low dose X-rays. The test is not painful and takes about 20 minutes. It will tell us about your muscle and fat distribution and how strong your bones are. (Bone mineral density not measured at Week 8)
- **Blood Pressure -** Your blood pressure will be measured using an automatic blood pressure monitor.
- **Questionnaires -** You will be asked to complete questionnaires related to your quality of life and dietary intake. These questionnaires will take between 5-10 minutes to complete.
- **Physical Performance & Strength Tests -** We will ask you to perform a number of tasks to assess your physical function, strength and balance such as a grip strength test using a hand held device. Other tests include a 4 metre walk to measure your gait speed, standing up and sitting back down in a chair 5 times or as many times as you can in 30 seconds and standing on one leg for example. These tests will take approximately 40 minutes all together. These tests are designed to be used in an older population and should not cause discomfort.

Phone Calls - Week 2, 6 & 10:

We will telephone you two weeks after your first visit to check how you are going with the study. We will then call you monthly to check your progress which should only take five minutes of your time.

Physiotherapist Visits – Visit 1, Visit 2, Visit 3 & Visit 4:
During the study we will ask you to come into HMRI every four weeks (visit 1, 2, 3 & 4) to see the physiotherapist to monitor and assess your exercise program.

Each time you come into HMRI for a clinic visit we will ask you to wear comfortable clothing suitable for light exercise.

12 Month Follow Up Visit – Visit 6

12 months after your last clinical visit (Visit 5) we will invite you to attend HMRI for a follow up visit (Visit 6). This is to see how your muscle mass, strength and function has changed after your participation in the trial. We will contact you by telephone to see if you are interested in participating. If you are interested, we will conduct some dietary, physical activity and health questionnaires over the phone. We will then arrange a suitable time for you to come into HMRI for a clinical visit.

The clinical visit will involve the same tests performed during the trial including body composition scans, a fasting blood test, blood pressure measurement, and strength and function tests. This follow-up visit should take no longer than 3 hours.

6. 'Are there risks to me in taking part in this study?'

- The side effects of having blood collected may include bleeding or bruising at the injection site and possible dizziness and/or fainting. Please advise the research team if you normally feel dizzy or faint when you have blood collected.
- This research study also involves exposure to a very small amount of radiation (DXA scan). As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. A DXA scan delivers <0.010 mSv. At this dose, no harmful effects of radiation have been demonstrated and the risk is negligible. The dose of radiation from this test is similar to the dose of naturally occurring background radiation that everyone is exposed to in two days. All radiation exposures will be carried out in accordance with the ARPANSA Code of Practice "Exposure of Humans to Ionizing Radiation for Research Purposes" (RPS8)". We would like you to tell us if you have participated in any research studies in the previous 5 years that have involved the use of radiation, as we need to make sure that you do not exceed a safe cumulative level of radiation exposure.

7. 'What happens if I suffer injury or complications as a result of the study?'
If you suffer any injuries or complications as a result of this study you should contact the study coordinator as soon as possible, who will assist you in arranging appropriate medical treatment.

8. 'How will my confidentiality be protected?'
Only the study investigators will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the study investigators will have access to your details and results that will be held securely at the Hunter Medical Research Institute.

9. 'What happens with the results?'
Blood test, body composition and bone mineral density results will be available to be sent to your general practitioner at your request. The results of the study will also be available to you at the completion of the study; however you should be aware that the study may take over a year to complete. We plan to discuss/publish the results of the study. In any publication, information will be provided in such a way that you cannot be identified. For all participants in the study we would like to access and record the visits in your medical records. This will involve our staff accessing your medical record and recording the results of your visit in your patient notes.

Blood samples collected in this study will be stored securely and may be used in further research only if you agree and the research has been approved by the Human Research Ethics Committee.

10. Costs

Participation in this study will not cost you anything. $100 will be given to each participant to cover the cost of the milk required for this study ($50 at visit 1 and $50 at visit 3). For participants required to use the nutritional supplement powder, this will be provided at no cost in one month supplies at visits 1, 2, 3 & 4.

Parking will not cost you anything and a parking space will be reserved for you prior to each visit.

11. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, one of the named researchers will discuss it and any queries you may have with you. If you would like to know more at any stage, please do not hesitate to contact him/her or any of the other investigators on the numbers listed.

Chief Investigator: Professor Lisa Wood
Priority Research Centre for Healthy Lungs
University of Newcastle. T: 02 4042 0147
E: Lisa.Wood@newcastle.edu.au

Study Coordinator: Isobel Stoodley
Priority Research Centre for Healthy Lungs
University of Newcastle. T: 02 4985 4563
E: Isobel.Stoodley@uon.edu.au

12. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Hunter New England Human Research Ethics Committee, reference number 2018/ETH00333. If you have concerns or complaints about the conduct of this study you should contact:

Dr Nicole Gerrand, PhD
Manager, Research Ethics and Governance Office
Level 3, The Pod,
Hunter Medical Research Institute (HMRI)
Lot 1, Kookaburra Circuit
New Lambton Heights NSW 2305
Tel: (02) 4921 4950
Email: HNELHD-ResearchOffice@health.nsw.gov.au

The Manager is the person nominated to receive complaints from research participants. You will need to quote reference number 2018/ETH00333.

Thank you for taking the time to consider this study.
If you wish to take part in it, please contact the study coordinator above.
This information sheet is for you to keep.

Prof Lisa Wood
School of Biomedical Sciences & Pharmacy
Hunter Medical Research Institute
Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Ph: 02 40420147 Fax: 02 40420046
Email: Lisa.Wood@newcastle.edu.au

Participant Consent Form (Participant Copy)

Sarcopenia Trial: Resistance training and Oral Nutrition in the Aging (STRONG Trial)

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the information statement, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to-

1) Completing the tests involved in the study
2) Completing questionnaires to obtain research data
3) A copy of my results being sent to my General Practitioner
4) Allowing research personnel access to my medical record and to record attendance and results in my file

☐ Secure storage of samples collected in this study to be used in future research, subject to approval by the Hunter New England Human Research Ethics Committee.

☐ Before, during and after photos taken throughout the trial

I consent to being contacted for a 12 month follow up visit YES ☐ NO ☐

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Name _____

Signature _____ **Date** _____

I have informed the above person about this research and am sure that they understand both the content of the Information statement and the additional information I have provided.

_____

Investigator/Delegate Name (printed)

Prof Lisa Wood
School of Biomedical Sciences & Pharmacy
Hunter Medical Research Institute
Lot 1 Kookaburra Circuit
New Lambton Heights NSW 2305
Ph: 02 40420147 Fax: 02 40420046
Email: Lisa.Wood@newcastle.edu.au

Participant Consent Form (Researcher Copy)

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_____

Investigator/Delegate Name (printed)