

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Muscle and tendon properties in healthy and stroke populations - MRI Professor Rob Herbert

Introduction

You are invited to take part in this research project, which is called muscle and tendon properties in healthy and stroke populations. The study is being conducted by Professor Rob Herbert, Dr Bart Bolsterlee, Dr Peter Stubbs and Mr. Arkiev D'Souza from Neuroscience Research Australia and Dr Jeanette Thom from The University of New South Wales.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved in taking part. Knowing what is involved will help you decide if you want to take part in the research.

What is the purpose of this research?

The aim of this project is to investigate the mechanical properties of muscles and tendons in the arm and leg. We hope to understand more about how the length and stiffness of muscles change with contracture after stroke and how that affects the ability to function.

Why have I been invited to participate in this research?

You are invited to take part in this study either because you have had a stroke and have contracture, or because you have not had a stroke and do not have contracture.

Description of study procedures and risks

If you decide to participate, you will be asked to sign the Participant Consent Form.

Attending the session

Description: Your involvement will involve attending the Clinical Research Imaging Centre at Neuroscience Research Australia for approximately one hour. Please wear comfortable clothing such as a loose top and pants/shorts.

Pre-scan questionnaire

Description: Before the scan you will be asked some questions so we can check if you have any conditions that would prevent you from having an MRI scan, such as presence of a pacemaker, metal pieces (e.g. from shrapnel or in association with metal work) or other metal implants.

Risks: We may need to exclude you from participation if you have any of the conditions that would prevent you from safely having an MRI scan. In the unlikely event we need to exclude you from the study you will still receive reimbursement for travel costs and \$50 for attending the session.

MRI scanning

Description: You will lie on a padded bed which is then slowly moved feet-first (or head-first) into an open chamber which generates the magnetic field (see figure). You will be required to remain still in the chamber for about 30 minutes until the scanning is complete. The leg, foot or upper arm will be placed in different positions during the scan.

Risks: The procedure is non-invasive and painless. MRI equipment has been frequently used in clinical practice for over 20 years and is approved by the Australian Therapeutic Goods Administration, the European Union and the USA Food and Drug Administration for this purpose.

The chamber is small and some people feel claustrophobic inside the chamber. (This is rare when scanning legs, but more common when scanning arms because then the head must go into the chamber as well.) If this occurs we will remove you from the machine and cease the experiment. You will still receive reimbursement for travel costs and \$50 for attending the session if we cease the experiment.

During the scan the scanner makes loud banging noises. Some people dislike the noise. We give all subjects ear-plugs or music with earphones to minimise disturbance. If you cannot tolerate the noise we will remove you from the machine and cease the experiment. You will still receive reimbursement for travel costs and \$50 for attending the session if this occurs.

We don't expect that the testing will be uncomfortable, but if you experience any discomfort you can ask us to stop the testing at any time.

There are no foreseeable risks in taking part in this study. However, there may be risks associated with this study that are presently unknown or unforeseeable.



After the MRI scan

Description: The scans will be assessed by certified radiologists.

Risk: A radiologist (medical specialist) will look at the images obtained during the scanning session and will provide a report. On rare occasions, MRI scans find unexpected diseases or abnormalities. It is standard policy to release the report to the researcher in charge of this study (Professor Rob Herbert) who would then be responsible for any follow up. If abnormalities are found, Professor Simon Gandevia would be responsible for advising you of the abnormal report and would organise with you to submit the report to your primary health care provider (e.g. your family doctor).

What are the possible benefits of taking part?

This study aims to further medical knowledge and may improve future treatment of people with contracture: We cannot and do not guarantee or promise that you will receive any benefits from this study.

What are the alternatives to participation?

Participation in this research is voluntary. If you don't wish to take part, you don't have to. Your decision not to participate will not affect your future relations with the University of New South Wales or Neuroscience Research Australia. The testing will not require any usual care or treatment to be withheld. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

Confidentiality and disclosure of information

By signing the consent form you consent to the research team collecting and using information about you for the research study. We will keep your data for 7 years. We will store information about you in a safe and a password protected server at Neuroscience Research Australia. Your information will only be used for the purpose of this research study and it will only be disclosed with your permission. It is anticipated that the results of this research study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you will not be identified.

Recompense to participants

Participation in this study will not cost you anything. We will cover the cost of travel to and from Neuroscience Research Australia with taxi vouchers and/or parking if required. We will also compensate you \$50 for your time on the day of participation.

Complaints

Complaints may be directed to the Ethics Secretariat, The University of New South Wales, Sydney 2052 (phone 02 9385 6222, email: humanethics@unsw.edu.au). Any complaint you make will be investigated promptly and you will be informed of the outcome.

How and when will I find out what the results of the research study are?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the box on page 4. If you tick the box we will provide you with a one page non-technical summary after the study is finished.

Your consent

Your decision whether or not to participate will not prejudice your future relations with the University of New South Wales or Neuroscience Research Australia. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

If you have any questions, please feel free to ask us. If you have any additional questions later, Professor Rob Herbert on 02 9399 1000 will be happy to answer them.

You will be given a copy of this form to keep.



THE UNIVERSITY OF NEW SOUTH WALES AND NEUROSCIENCE RESEARCH AUSTRALIA

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM (continued)

**Muscle and tendon properties in healthy and stroke populations – MRI
Professor Rob Herbert**

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

.....
Signature of Research Participant

.....
Signature of Witness

.....
(Please PRINT name)

.....
(Please PRINT name)

.....
Date

.....
Nature of Witness

I would like to receive a summary of findings from the study when it is completed.

REVOCATION OF CONSENT

**Muscle and tendon properties in healthy and stroke populations – MRI
Professor Rob Herbert**

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with The University of New South Wales or Neuroscience Research Australia.

.....
Signature

.....
Date

.....
Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Professor Rob Herbert
Senior Principal Research Fellow
Neuroscience Research Australia
PO Box 1165
Randwick NSW 2031
T | + 61 2 9399 1000
E | r.herbert@neura.edu.au