PLAIN LANGUAGE STATEMENT AND CONSENT FORM

TO: Participants

Plain Language Statement

Date: 11.11.2016
Reference Number: HEAG-H 194_2016
Full Project Title: Spine and GravityFit exercise
Principal Researcher: A/Prof. Daniel Belavy
Associate Researchers: Richard Scheuring (NASA, USA) Dr Timo Rantalainen (Deakin) Dr Nicky Ridgers (Deakin)

This Plain Language Statement and Consent form is 9 pages long. Please make sure you have all the pages.

Your Consent

You are invited to take part in this research project.

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 so that you can make a fully informed decision whether you are going to participate.

Please read this Plain Language Statement carefully. Feel free to ask 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. Please feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.
Purpose

The GravityFit whole body exercise device (www.gravityfit.com) is used to strengthen deep and postural muscles of the body. The manufacturer has asked the research team Deakin to conduct research with this exercise approach for justifying its use in astronauts. Astronauts are typically aged between 33 and 55 when they fly into space and are in top physical condition.

You have been invited to participate in this study because you are aged between 33 and 55, are a highly fit individual and are free of any health conditions that might affect your spine.

This research involves two aspects. One aspect (‘day 1’) is to assess whether the exercise approach can indeed activate the deep stabilising muscles of the trunk. On the International Space Station there are exercise devices for astronauts to perform abdominal crunches, but otherwise no opportunity to exercise the other muscles of the spine. This aspect of the study will investigate whether the exercise approach with the exercise apparatus preferentially activates the deep muscles of the abdomen and back and how this activation changes with different loading levels. You will be asked to perform a series of exercises with the exercise device in the magnetic resonance imaging (MRI) scanner and images will be taken at rest and also whilst holding the contraction. All exercises will be of low intensity, meaning that you will not perform maximal contractions or continue muscle exertion until exhaustion.

The second aspect (‘day 2’) is to examine how efficiently the exercise approach can prevent water entering the discs in the spine when you lie down for two hours. Lying down minimises the effect of gravity on the body, and is used by space agencies to replicate the impact of microgravity experienced by astronauts. For example, when we wake up in the morning, our spine is longer than before we go to bed the night before. This is because, when we do not load the spine, the discs swell up. In astronauts, this is thought to be the reason why they are more likely to injure their backs after spaceflight. For this reason, this aspect of the project will examine whether the exercise approach, in comparison to doing no exercise, can prevent or reduce the swelling of the discs during two hours of lying. You will be randomised (allocated by chance) to either a group that performs the exercise lying or a group that performs no exercise in lying.

You are not required to participate in both aspects of the project.

Methods and Demands: what you will be asked to do

If you participate in the study, the procedure is as follows: an appointment will be made for you to attend the magnetic resonance imaging scanning facility located here:

Imaging @ Olympic Park
AAMI Park, 60 Olympic Boulevard
Melbourne, VIC 3004
www.goo.gl/HJndZz

Directions to the scanning facility:
• By car: When coming down Swan St (from Richmond end) and after crossing Punt Road, turn left at first set of lights in Swan St (Entrance F). There is parking on the grounds which is free of charge for people attending the scanning center. Bring the parking ticket in for validation when you come.
• By tram: Route 70, get off at Stop 7D AAMI Park (~150m from scanning center)
• By train: Richmond Train Station (~600m from scanning center)

For the testing session, please ensure you have comfortable clothing which enables us to see your shoulders and shoulder blades. This will be particularly important for the postural assessment done as part of the testing protocol.

Please ensure there are no metallic objects on your clothes or underwear, otherwise we may need to give you a gown to wear for the scanning. Please refrain from wearing jewellery where possible especially earrings, most other piercings will not affect the images.

When you arrive, you will be met by a member of the investigative team to explain the procedure and clarify any further questions you may have. You will complete a form for the scanning centre and be instructed on how the testing session will be conducted.

Then the following testing procedure for the first aspect of the project ('day 1': examining muscle contraction with GravityFit exercise) will occur:

1. You will be given questionnaires to complete. These questionnaires will ask about what kinds of physical activity you do or have done and other factors relevant to the outcomes of the study (e.g. body height, gender, occupation)
2. Your body weight and height will be measured.
3. A series of postural assessments will be done. These will involve taking a photo of your body posture in specific positions.
4. You will be instructed in performing the exercises that you will perform in the scanner.
5. Then you will enter the magnetic resonance imaging scanner and a series of scans will be performed to measure different parameters of different structures in the spine. Magnetic resonance imaging is a way of getting pictures of various parts of your body without the use of any radiation.
   a. In a sub-sample of participants (seven participants), we will perform measurements of the shoulder rather than the spine.
6. Following the instructions of the operator, you will do the exercises and the scans will be performed.
7. It is anticipated that the scanning protocol will be over within 40 minutes

After the scanning, you will be given a waist worn accelerometer and a thigh worn step-tracker to wear for 8 days. This accelerometer is to be worn the entire time and only to be taken off when showering or doing any water based activities. The device can be taken off when you sleep, but does not need to be. We will supply you with a reply-paid envelope to send the accelerometer back to us.
Image of the GravityFit exercise apparatus in lying. The exercise apparatus spans from your head to the shoulders and feet to provide ‘compression’ along the body. By extending and bending your arms, you can alter the load applied. The exercises are performed at low load whilst maintaining spine and trunk posture.

The second aspect of the project (‘day 2’; exercise in lying and preventing disc expansion) will follow a similar procedure, except that after the initial scanning, you will spend 2 hours in lying. During this time, you will either (a) perform no exercise or (b) will perform the GravityFit exercise protocol. Whether you perform exercise or not will be decided by chance and the study staff will have no influence on this. At the end of the lying period, the scan will be repeated. Similar to ‘day 1’ you will be given an accelerometer to wear for 8 days and return to us.

**Potential benefits to participants**

We cannot guarantee or promise that you will receive any benefits from this project. By participating in this project, you could gain access to information on your own body, via the magnetic resonance imaging scans, that you would otherwise not have.

**Potential risks to participants**

This study is considered low risk by the investigative team.

Magnetic resonance imaging has no known risks when standard screening procedures are implemented. You will be asked specific questions regarding things that might preclude you from having a magnetic resonance imaging scan (e.g. becoming nervous in enclosed spaces, any metal implants or fragments, any electronic implants such as a pacemaker, piercings that cannot be removed, possible pregnancy).

If you have a tattoo, there is a slight risk you may get skin irritation (like a sun-burn) due to the magnetic fields in the scanner. Some older tattoos and also black-inks may contain iron in the colours used. In the MRI, the magnetic field can cause heating of the iron compounds. This heating may cause skin irritation. As part of screening for this study, we will clarify what kind of tattoo you may have, if any.
Physical activity monitoring has been done extensively without any adverse effects. There is the potential for skin irritation from the accelerometer strap and/or hospital grade dressing used to affix the monitors.

There may be additional unforeseen or unknown risks.

**Expected benefits to the wider community**

The findings of this study will help the wider community to understand what kinds of physical exercises are better for keeping the spine healthy.

**How privacy and confidentiality will be protected**

Any information obtained in connection with this project and that can identify you will be remain confidential. It will only be disclosed with your permission, subject to legal requirements.

Forms with identifying information will be stored in a locked filing cabinet in the researcher’s office or in a password protected electronic file.

A unique code will be used on all forms and data collected from you, and not with your name or any other identifying information. These data will be stored on a password protected Deakin server.

Only the investigators at Deakin University will have access to the data. Sharing of data with investigators outside of Deakin University or with the GravityFit company will occur only in a coded, anonymised way and no identifying or personal information will be shared. Photos taken during the postural assessments will be de-identified (i.e. your face and any identifying body markings, such as tattoos, will be blacked out).

None of the information provided will be made public in any form that would reveal a participant’s identity to an outside party, thus all participants will remain anonymous. The results of this project will be presented at scientific conferences, in scientific journals and research theses. In all cases your identity and personal information will not be disclosed. Information will be provided in such a way that you cannot be identified.

Data will stored for a period of 5 years after publication, after which it will be destroyed. 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.

**Dissemination of the research results**

On request, a summary of the project will be e-mailed to you at the completion of the study. If you wish, you will also be able to obtain a copy of the magnetic resonance images after the completion of the testing session.
As part of normal magnetic resonance imaging routine, if we by chance see any abnormal findings, you will be advised on this and an appropriate course of action, such as to speak to a medical doctor.

The results of this study will be presented at research conferences and communicated in scientific journals.

**How the research will be monitored and conducted?**

A/Prof. Daniel Belavy will be primarily responsible for all aspects of the implementation of the project.

Richard Scheuring is involved in the treatment of astronauts at NASA with spinal problems and is acting as a clinical advisor for this project.

Dr Timo Rantalainen will assist with data analysis.

Dr Nicky Ridgers will advise on physical activity monitoring.

A research assistant will implement the testing and exercise protocols with you and will also conduct data analysis. Another research assistant will manage the accelerometer and step-tracker.

**Any payments to participants?**

For completion of the first testing session (‘day 1’) participants will receive a pre-paid Visa card charged with $60, which can be used wherever a Visa card is accepted. For completing the second testing session (‘day 2’) participants will receive a $100 pre-paid Visa card.

**Sources of funding for the research**

This research is funded by a grant from GravityFit to Deakin University.

**Financial or other relevant declarations**

The researchers involved in the study do not have any interests, financial or otherwise, that conflict in the conduct of this study.

**Participation is voluntary**

Participation in this 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.

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. You will also have the option 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. 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 Revocation 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.

**Contact details**

If you require further information or wish to withdraw your participation from this project, you can contact the principal researcher:

**A/Prof Daniel L. Belavy**
School of Exercise and Nutrition Sciences
Deakin University
Melbourne Burwood Campus
221 Burwood Highway
Burwood, VIC 3125

**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:

The Manager, Ethics and Biosafety, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number *HEAG-H 194_2016*. 
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Date:
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I have read, or have had read to me, 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 consent to participate in the following testing protocols, as described above:

☐ Day 1  ☐ Day 2

Please indicate below whether you agree to have your contact details stored to be invited to participate in future research.

☐ Yes, I would like to be invited to participate in future research.

Please tick the box below if you would like to receive a copy of the study results, via email, at the end of the study.

☐ Yes, I would like to receive a copy of the study results via email.

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.

Participant’s Name (printed) ……………………………………………………………………
Address ………………………………………………………………………………………...
…………………………………………………………………………………………………
Best contact telephone ………………………………………………………………………
Signature …………………………………………… Date

Please email or fax this form to:
A/Prof Daniel Belavy
spine@deakin.edu.au
Fax: +61 3 9244 6017
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TO: Participants

Withdrawal of Consent Form

(To be used for participants who wish to withdraw from the project)

Date:

Full Project Title: Spine and GravityFit exercise
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I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Deakin University.

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

Signature ………………………………………………………………………………… Date …………………..

Please email or fax this form to:
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