



PARTICIPANT INFORMATION SHEET

Cognition and Type 2 Diabetes in Older Tasmanians A Randomised Control Trial of Exercise

Invitation

You are invited to participate in a research study into whether a six month exercise program is beneficial in preventing decline in thinking and measures of brain health in people with type 2 diabetes aged 50-75 years.

The study is being conducted by:

Dr. Michele Callisaya: Monash University; University of Tasmania
A/Prof Velandai Srikanth: Monash University; University of Tasmania
A/Prof James Sharman: University of Tasmania
A/Prof Thanh Phan: Monash University
Prof Tim Greenaway: Royal Hobart Hospital; University of Tasmania
Prof David Bruce: University of Western Australia
Prof Robin Daly: Deakin University

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?'

The purpose is to investigate whether a six month exercise program is beneficial in preventing decline in thinking and measures of brain health in people with type 2 Diabetes.

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

You are eligible to participate in this study because you:

1. Have type 2 Diabetes
2. Are between 50-75 years
3. Are not exercising more than the equivalent of 30 minutes once per week in the last three months.



We hope to recruit 50 participants in total.

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.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study. 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.

4. ‘What does this study involve?’

This study will be conducted over 6-7 months.

Screening visit 1

If you agree to participate in this study, you will be asked to attend a screening appointment and to sign the Participant Consent Form. This initial visit will take place at the Menzies Research Institute Tasmania where you will also be:

- Given the opportunity to ask any questions before signing the consent form.
- Assessed by a doctor for your medical suitability for exercise including a measuring your heart rhythm (ECG) and the doctor phoning for pathology results relating to your kidney function.

Screening visit 2

- A fitness stress test on a treadmill whilst wearing a mask to measure oxygen. Your heart rate and blood pressure will also be measured during this test.
- A scan of your heart (echocardiographic imaging) at rest and in some instances after exercise will be performed.
- A urine test to measure your kidney function before and after the fitness test.

After screening, you will be given appointments for a brain MRI scan at the Royal Hobart Hospital; and to attend a clinic for baseline tests (described below).

Clinic 1

You will be asked to attend a morning clinic at the Menzies Research Institute Tasmania in Hobart. This will take about 4 hours, and the following tests will be undertaken:



- Questionnaire (asking about education, occupation, smoking, health problems, quality of life, mood, diabetes management, medications, diet, family history of diabetes, physical activity levels, your confidence in starting an exercise program and your ability to perform daily activities). This can be filled in at home and brought to the clinic appointment.
- Measures of muscle strength, balance and walking speed.
- Measure of physical activity (using accelerometers that count the number of steps walked per day and intensity of activity).
- Measures of blood pressure (at rest), height, weight, and waist circumference.
- Measures of thinking and reasoning ability.
- Samples of blood taken from a vein will be taken to obtain vascular markers such as glucose, insulin and cholesterol levels. The amount of blood taken will be equivalent to 40 millilitres.
- This blood sample will also be used to store a DNA sample that will be used to study the effect of genes on brain ageing.
- Retinal photograph (of blood vessels in the eye). This involves looking into a camera and is painless.
- Measures of central blood pressure over 24 hours (this is assessed by wearing a monitor and is not invasive).
- A measure of blood flow in the skin with a non-invasive laser (Laser Doppler Flowmetry).

MRI brain scan

The scan will take place at the Royal Hobart Hospital Imaging Department and take approximately 60-90 minutes. MRI scans are safe and not associated with radiation. The MRI will be performed at a separate time from the other measures.

Participants will then be randomised into one of two different types of exercise.

Definitions of ‘randomized trial’

Sometimes health professionals don’t know the best way of treating patients with a particular condition so comparisons need to be made between different treatments. To do this, study participants are put into groups and given different treatments, and the results are compared to see whether one treatment is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the health professionals nor the study participant can decide which treatment the participant receives.

You will be told which exercise group you are in after the clinic assessment. However, you won’t know what exercises the other group receives.



Exercise program

Participants will be asked to exercise for 1 hour, 3 times a week for 6 months. Two of these exercise classes will be supervised by a qualified Exercise Physiologist or Physiotherapist at the Menzies Research Institute Tasmania. There will be other people in each class who will also be participating in the study. There will usually be a choice of a morning or an afternoon session.

Two classes per week will be held at the Menzies Research Institute Tasmania and one session can be completed at home and logged in an exercise diary.

You will be asked not to change any other lifestyle factors (eg diet or start any other exercise programs)

Clinic 2 – Follow up assessment

The same clinic measures and MRI brain scan will be taken after the 6 month exercise program.

5. ‘How is this study being paid for?’

This study is being funded by grants from Alzheimers Australia Research Dementia Fund. The funding bodies do not have any role in the design of implementation of the study and cannot influence the results. All of the money being paid by the funding body to run the trial will be deposited into an account managed by the University of Tasmania and Monash University. No money is paid directly to individual researchers.

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

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

- Approximately 40 mls of blood will be collected which may result in temporary discomfort and bruising.
- Very rarely, people may find the MRI scan uncomfortable due to the small space and noise of the scanner.
- Occasionally people may get fatigued while performing the cognitive or thinking tasks and appropriate breaks will be provided to offset this.



- Although exercise stress testing is regarded as a safe procedure, there are reports that the test may induce a heart attack or cause sudden death. The chance of sudden cardiac death occurring during this test is estimated to be from 0 to 5 per 100,000 tests (*Fletcher GF, et al. Circulation. 2001;104(14):1694-1740*). Before participating in the exercise test you will be screened for the presence of factors for which exercise testing is contraindicated – if present, exercise will not be undertaken. In the event of a medical problem after the maximal exercise test, trained personnel will be present to render assistance if required.
- Exercise may result in temporary muscle stiffness or very occasionally injury. There are reports that exercise may induce a heart attack or cause sudden death, but again this is very rare. Classes will be supervised by qualified professionals to minimise any risk.

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 investigators as soon as possible - they will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

8. ‘Will I benefit from the study?’

The testing will not provide you with any direct benefit because the link between you and your sample/tests will be removed. However, it may provide valuable information to improve the management of people with Type 2 Diabetes in the future.

9. ‘How will the DNA sample be used?’

The DNA sample will be used to test for the ApoE gene. Although this gene has been associated with risk of disease including Alzheimers, testing for it is not part of routine



clinical care. Currently available genetic tests for ApoE 4 do not reliably aid in predicting who will develop Alzheimer's disease. Because of this genetic results obtained through this research will not be fed back to participants.

10. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything. Breakfast will be provided during initial and final testing. You will be given a \$50 shopping voucher at 2, 4 and 6 months for attending the exercise sessions. There will be no other payments.

11. 'What will happen to my tissue sample after it has been used?'

The blood or tissue sample/s you provide during the study will be destroyed 7 years after the completion of the study. If the researchers wish to store (or 'bank') the samples for a longer period, you will be asked whether you agree to this and, if so, will be asked to sign a specific consent form.

If you do agree to your tissue samples being stored, they will not be used for other research projects, except with your written consent and with the approval of a Human Research Ethics Committee at that time.

12. 'How will my confidentiality be protected?'

Of the people treating you, only those named above or necessary others (eg nursing or exercise staff involved in the study) 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 researchers named above or the study staff (where appropriate) will have access to your details and results that will be held securely at the Menzies Research Institute Tasmania.

13. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to publish the results in peer-reviewed journals, presentation at conferences or other professional forums). In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.



14. ‘What happens to my treatment when the study is finished?’

The exercise instructors will not be available after the study finishes.

You may be able to continue the exercises at home following completion of this study if it found to be of benefit to you.

15. ‘What should I do if I want to discuss this study further before I decide?’

When you have read this information, the Study Coordinator Kate Butorac will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on (03) 6226 7766 or email kbutorac@utas.edu.au

16. ‘Who should I contact if I have concerns about the conduct of this study?’

This study has been approved by the Tasmanian Health and Medical Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 7479 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote H0013664.

**Thank you for taking the time to consider this study.
This information sheet is for you to keep.**