PARTICIPANT INFORMATION SHEET - CLINICAL TRIAL

Standing Tall COgnition and Gait: A Randomised Control Trial (Standing Tall COG)

Invitation

You are invited to participate in a research study into whether a six-month balance and cognitive training program is beneficial in preventing decline in mobility, balance and thinking.

The study is being conducted by:

Dr. Michele Callisaya: University of Tasmania and Monash University
A/Prof Kim Delbaere: Neuroscience Research Australia
Dr Maree Farrow: University of Tasmania
Prof Velandai Srikanth: University of Tasmania and Monash 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 6-month balance and cognitive training program is beneficial in preventing decline in mobility, balance and thinking.

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

You are eligible to participate in this study because you:

a. Are over 60 years of age and have been either diagnosed with cognitive impairment by a health professional OR you have noticed a decline in your memory or thinking ability;
b. Are not already participating in another exercise program designed to improve thinking or balance;
c. Don't have a neurological condition such as Multiple sclerosis, Parkinson's disease, dementia or a stroke;
d. Can walk around your house without a gait aide or use of the furniture;
e. Perform most activities of daily living independently;
f. Are willing to participate in the program for 6 months and attend the pre and post assessments at the Menzies Institute for Medical Research.

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

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.

4. *'What does this study involve?'*

This study will be conducted over 6 months.

Initial visit

You will be asked to attend an appointment and sign the Participant Consent Form. This initial visit will take place at the Menzies Institute for Medical Research where you will you will be given the opportunity to ask any questions before signing the consent form. The appointment will take approximately 2 hours. This assessment will be repeated 6 months later to see if there is any change.

You will also be asked to

- Return a questionnaire (asking about education, smoking history, health problems, mood, medications, and your ability to perform daily activities)

- Have the following assessed:

  a. Walking and balance ability – alone and while doing a talking task;

  b. Tests of cognitive ability (thinking, memory and reasoning);

  c. Tests of strength, vision and reaction time;

  d. Measurements of height, weight and blood pressure.

On completion of the assessment you will be placed at random (like tossing a coin) into one of two groups - the exercise group or the control group.

You have a 50% chance of being allocated to the exercise group and a 50% chance of being allocated to the control group. Neither the health professionals nor the study participant can choose which treatment the participant receives. It is not possible to change groups.

We will let you know which group you are in the week following the assessment. If you are in the exercise group, after 6 months you will also be asked about how the program was to use.

What if I am in the exercise group?

A trained professional will come to your home (for approximately 1 hour) and show you the Standing Tall exercises. They will set up the program in an appropriate location in your house. A tablet style computer will be used to help remind you how to do the exercises (pictures/videos) and also will progress the exercises automatically as you improve. You do not require any prior experience using a tablet style computer.

You will be asked to build up from 40 minutes to 120 minutes per week over a 6-month period (this can be done in shorter time periods eg 15-20 minutes daily). The trained professional will visit your for approximately ½ hour at least 2 times (in the first and second month) and also phone you in months 1, 3, 4 and 5 to check how you are going. If you have any problems or questions you can phone this person and if necessary they will come and visit you again at home.

Health Education group

You will receive health information sheets in the post every month for 6 months. You will not receive the exercises. You will be asked to continue with your normal activities. We will phone you at approximately months 1, 2, 3, 4 and 5 to see if you have any questions regarding the health information sheets.

Both groups will be sent a questionnaire asking about whether they have had a fall each month.

5. *'How is this study being paid for?'*

This study is being funded by a grant from the National Health and Medical Research Council. The funding bodies do not have any role in the design or 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. There are no current financial benefits to the investigators or sponsors. The application may be commercialised to make a profit in the future by Neuroscience Research Australia who will host the app.

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

There may be risks associated with this study that are presently unknown or unforeseeable.
The known risks of this study are:

- Occasionally people may get fatigued while performing the cognitive or thinking tasks and appropriate breaks will be provided to offset this;
- Exercise may result in temporary muscle stiffness or very occasionally injury or a fall. You will be assessed by a trained professional to minimise risks.

7. *'What happens if I suffer an 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 equipment, or by the negligence of one of the parties involved in the study (for example, the researcher). 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 or they will be paid direct to the provider. 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 tests will be removed. However, it may provide valuable information to improve the

management of people with thinking or memory complaints in the future. You may obtain health benefits from the intervention, although this is not yet known.

9. *Participation in this study will not cost you anything and you will not be paid.*

10. *'How will my confidentiality be protected?'*

Only those named above or necessary others (eg research assistant or exercise trainers) 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. Results will be held securely at the Menzies Institute for Medical Research, University of Tasmania. With your permission we will let your GP know you are participating in the study.

It is important to disclose that the The 'Standing Tall' app is hosted by Neuroscience Research Australia (NeuRA; Randwick NSW). Both NeuRA and the app developers (The Project Factory, Surry Hills NSW) will offer technical support to the investigators throughout the trial. To enable prompt and efficient support, both institutions will be able to access backend data via a password. This information is de-identified (e.g. you cannot be identified) and only includes your participant ID and exercise data (e.g. the amount of time you exercise and the difficulty of the exercises). The information will only be used to support the study and they will not have access to any other information about you.

11. *'What happens with the results?'*

If you give us your permission by signing the consent form, we plan to publish the results in peer-reviewed journals, and present results at conferences and 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. If other researchers would like to access our data your name and any identifying information will be removed.

12. *Personal study results:*

If your personal study results indicate further investigation (e.g. high blood pressure) we are able to send these to your GP with your permission. You will need to sign a separate consent form for this.

13. *'What happens to my treatment when the study is finished?'*

The exercise application and trainers will not be available after the study finishes.

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

When you have read this information, the Research Assistant will discuss it with you and any queries you may have. If you would like to know more, please do not hesitate to contact them on (03) 6226 7766 or email Standing.Tall@menzies.utas.edu.au .

15. *'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 you should contact the Executive Officer of the HREC (Tasmania) Network on (03) 6226 6254 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 [H0016983].

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