PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

"SmartSTEP Stroke: A cognitive-motor step exergame program for improving balance and mobility in stroke survivors"

A/Prof Jasmine Menant

1. What is the research study about?

This research study will find out whether playing challenging stepping games (Figure 1) for 4 months can improve balance and mobility after stroke. This exercise program targets cognition (thinking) and balance. It is done at home. This study will also test whether this exercise program can:

- Improve focus and attention
- Improve quality of life and physical activity levels.

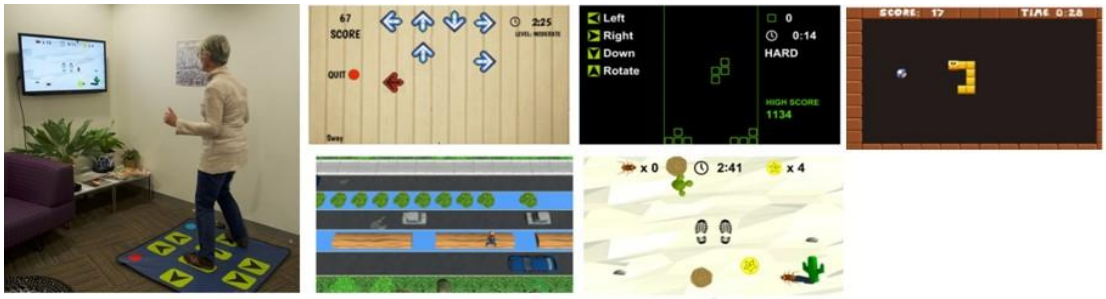

Figure 1. Set-up for the stepping games device and examples of games that will be played: Stepmania, Tetris, Anaconda, Toad Runner, La Cucaracha.

2. Who is conducting this research?

The study is being carried out by the following researchers:

Role	Name	Organisation
Chief Investigator	Associate Professor Jasmine Menant	NeuRA, UNSW
Co-Investigator/s	Professor Stephen Lord	NeuRA, UNSW
	Ms Kulvara Lapanan (PhD Student)	NeuRA, UNSW
	Dr Lloyd Chan	NeuRA, UNSW
	Associate Professor Daina Sturnieks	NeuRA, UNSW
	Dr Ken Butcher	The Prince of Wales Clinical School, UNSW

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part.

You can take part in this study if you are:

- 18 years or older;

4. **at least 6 months post stroke (ischemic or haemorrhagic);**

- living in the community;

- experiencing balance or mobility impairment.
- have access to a smart device /computer and to the internet /Wi-Fi;
- are able to communicate in English or accompanied by a carer who can;
- are able to provide informed consent;
- are willing and able to follow all the study rules, including the training, the timing and nature of required tests.

You cannot take part in this study if you:

- are unable to independently walk 20 metres;
- are unable to independently undertake the choice stepping reaction time test;
- have significant cognitive impairment;
- experience severe visual impairment;
- have neurological conditions in addition to stroke, or any medical condition that prevents safe exercise participation;

Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.
If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

If you agree to participate you will be asked you will first be asked to sign the Participant Consent Form.

This study will be conducted over four months and will involve 86 participants. Please see the following research procedures (Figure 2).

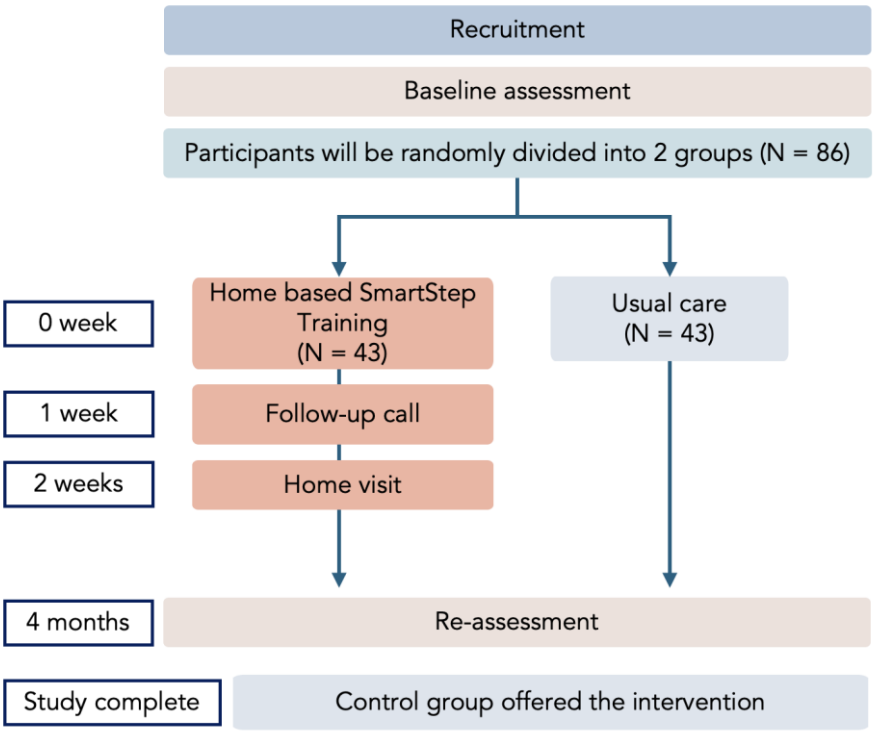

Figure 2. Study flow.

QUESTIONNAIRES: you will be sent a set of online questionnaires to fill in at the start of the study and then at four months. These questions give us information on your stroke, basic health, quality of life, depression, concern about falling, physical activity and past falls. This will take approximately 30 minutes to complete.

ASSESSMENTS: The research team will invite you to visit NeuRA in Randwick or a Community Centre on the Central Coast on two occasions. Each visit will take approximately 1.5h to 2 hours. During each visit, you will be asked to undertake:

- Balance and fall risk assessment: You will undertake simple physical tests to check your vision, sensation, leg muscle strength, reaction time and standing balance. We will also ask you stand up from a chair, walk 3 meters, turn around, walk back, and sit down.

- Cognitive assessment: We will ask you to complete two small tests designed to test different brain functions and different areas of thinking.

- Mobility and brain activity assessment: You will be fitted with the fNIRS (functional near-infrared spectroscopy) system to measure brain function while performing walking tasks. You will be required to wear a cap fitted with small optical sensor devices (optodes) and a small backpack

holding the recording system. This is a safe and non-invasive method. The process of placing the optodes on your scalp can cause minor discomfort, but this is uncommon. You will be asked to step on targets displayed on a step mat according to commands presented on a computer screen.You will then be fitted with a harness for your safety before being asked to walk on a treadmill, for 3 to 5 min. While walking at a self-selected comfortable speed, you will be instructed to step and avoid stimuli displayed as lit squares (green and red squares) on the surface of the treadmill.

You'll have rest breaks between each assessment. During these assessments, you'll be recorded on video with a smart tablet and asked to wear a wristwatch and a waist sensor that tracks your movement patterns. The camera angle will be set up to purposely avoid showing your face.

At the end of the study, you will receive feedback on your results.

PHYSICAL ACTIVITY TRACKING: we will record your physical activity levels with a wrist watch that we will provide. You will be asked to wear the watch for a week whilst doing daily activities, at the start of the study and at four months.

FALLS: over the four-month study, we will send you a weekly text message to ask you whether you have had a fall in the past week.

INTERVENTION: after the initial assessment, you will be placed into one of two groups at random (like the flip of a coin):

- The control group (usual care) : will be asked to go about their daily life 'as normal' for the duration of the study. You will be offered the four-month exercise program with supervision from research assistants at the end of the study (after having completed the four-month re-assessment).

- The exercise group: will get a computer and step mat (Home-based SmartStep training system). On a visit to your home, the researcher will set up the system. They will also teach you how to use it safely. They will ask you to play the games while standing and stepping on the mat. We recommend you to play in short 20- to 30-minute sessions 3 – 4 times a week and build up to a total of 120 minutes/week for four months. The researcher will organise phone or video calls with you on week one and home-visit on week 2 to make sure that you are safe during training. They will also talk to you about your progress and moving up through the games and any issues that you may have. There is also a telephone service should you require help with the equipment.

The training system is made of a Bluetooth connected (wireless) step mat and a mini personal computer with custom software including eight games. The computer is connected via HDMI cable to display on either the home television or a computer monitor (provided as needed). The training system does not require approval from the Australian Therapeutic Goods Administration because it is not designed to treat a disease but to train stepping and balance. It has already been tested in large studies of older people, people with Parkinson's disease and people with Multiple Sclerosis. They found it safe and enjoyable. A researcher will visit your home to collect the training equipment at the end of the four months training.

The SmartStep training program, is a novel approach developed to enhance balance and mobility in people at risk of falls. Its prior applications have focused on research settings, where it has been shown to reduce falls by 26% in older people and improve balance and mobility in people with neurological conditions, such as Parkinson's disease and Multiple Sclerosis. This trial is investigating the use of the SmartStep training program in stroke survivors, specifically in a home-based setting, to determine its safety, acceptability, and effectiveness for improving balance and mobility following a stroke. This differs from previous stroke research, which primarily evaluated effectiveness of traditional rehabiiltation under supervised conditions in clinical or research environments.

The trial will be monitored by the Steering Committee consisting of the Chief Investigators.

Possible risks in taking part in this study:
Known risks while you are in this study are: muscle strain, muscle ache, chest pain, marked breathlessness, joint pain that worsens, losing balance or falling while doing the tests or during the home step training sessions. If you feel any of these symptoms or any new serious symptom of concern, or if you fall or feel unwell, you should stop exercising and let the study chief investigator know. Appropriate supervision will minimize this risk during the tests. If you are in the exercise group, the training equipment will be set up in a safe and appropriate area in your home. The visiting researcher will provide safety education to minimise the risk of pain or injury.

During the study, if you have had a bad fall, or feel faint or dizzy during exercise, first make sure you are in a safe and comfortable position; sit down on a sturdy chair; or stay on the floor if you cannot get up on your own. Then call for help, ring 000 for an ambulance, and contact a close family member or friend to notify them of the emergency.

The risk of these harms and discomforts are minor. The study protocol will be carried out by trained research assistants.

There may also be risks related to this trial that are presently unknown or unforeseeable.

Additional Costs and Reimbursement: There are no costs associated with participating in this research project, nor will you be paid. We will however compensate for the costs of travel to NeuRA for baseline and re-assessments by providing AU$ 50 prezzee gift card at each visit.

6. What are the possible benefits of taking part?
We cannot guarantee or promise that you will get any benefits from this research. However, you may find that you have improved balance and that you can move better. You may also find that your thinking and memory abilities have improved and you have better quality of life. We hope we can use the findings of this study to create a rehabilitation program that will help stroke survivors move around better and enjoy a good quality of life.

7. What are the alternatives to taking part in the research?
You do not have to take part in this research project to receive treatment in a hospital. Other exercise and rehabilitation options are available, you can discuss them with your local doctor.

8. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study.

The research team will store the data collected from you for this research project for a minimum of 15 years after publication of the research results.

The information about you will be stored in a non-identifiable format where your identity will be unknown.

You will be asked to provide your consent for the research team to share or use the information collected from you in future research that:

- Will be specific to the aims of this research;
- Will be an extension of, or closely related to, the original project; or is in the same general area of research;
- Will be used in any future research.

Your information will only be shared in a format that will not identify you.

- Information collected from you in an electronic format will be stored in a password protected folder on the NeuRA server and only accessible to the approved research investigators.
- Information collected from you using paper-based measures will be stored in a locked cabinet in the office of Kulvara Lapanan and only the approved research investigators will have access to this information.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by NeuRA, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how NeuRA protects personal information is available in the NeuRA Privacy Policy.

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

The research team intend to publish and/ report the results of the research. All Information will be published in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

10. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with NeuRA or UNSW Sydney. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

11. What if I have a complaint or any concerns about the research study and will I receive compensation if suffer any injuries or have complications?

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Complaints Contact

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
iRECS Reference Number	HC 7307

12. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member of the research team:

Research Team Contact Details / Chief Investigator

Name	A/Prof Jasmine Menant
Position	Senior Research Scientist
Telephone	02 9399 1267
Email	j.menant@neura.edu.au

Support Services Contact Details

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	**Beyond Blue** (free 24-hour phone support or web chat 3-12pm AEST)
Web	https://www.beyondblue.org.au
Telephone	1300 22 4636

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only;
- ☐ 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 study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I understand that I will be given a signed copy of this document to keep.
- ☐ I understand that the results of the research will be made available on the NeuRA website.
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.

Name: _____

Address: _____

Email Address: _____

Optional Consent for reuse of data and future research:

- ☐ I provide my consent for the information collected about me to made available to other researchers as described at section 7 of this document.
- ☐ I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

+An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales or Neuroscience Research Australia.

WITHDRAWAL OPTIONS
Please tick one:

- ☐ I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.
- ☐ I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.
- ☐ I am withdrawing my consent and I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	A/Prof Jasmine Menant
Email:	j.menant@neura.edu.au
Phone:	02 9399 1267
Postal Address:	Neuroscience Research Australia, Margarete Ainsworth Building, Barker street, Randwick, NSW 2031.