FAH018178

Austin Health

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Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Austin Health – Austin Repatriation Hospital

Title	Can Real-time Biofeedback of Foot Clearance Data Assist with Gait Rehabilitation following Stroke?
Short Title	Biofeedback Training in stroke patients
Protocol Number	1
Project Sponsor	NHMRC
Coordinating Principal Investigator/ Principal Investigator	Prof Rezaul Begg (CPI) / Dr. Catherine Said (PI)
Associate Investigator(s)	Prof Farees Khan, Prof Mary Galea, Dr Pazit Levinger, Dr Lisa James, Dr Tony Sparrow
Location	Austin Health – Austin Repatriation Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have had a stroke more than 6 months ago. The research project is testing a new method of retraining walking to prevent tripping and falling.

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

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor or other healthcare worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to participate in the research processes that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This research has been funded by the National Health and Medical Research Council (NHMRC). The purpose of this project is to see whether giving you information about how your foot clears the floor while you are walking (feedback) changes the way you walk. This is important as very low foot clearance while you are walking could lead to a fall. We know that people who have not had a stroke can change the way they walk using this information. We also know that feedback can help people with stroke with other movements and activities. We recently found this method helped increase foot clearance in 5 people who had a stroke and we would like to now determine if this method is useful in a larger sample of 150 people. This research is a joint collaboration between Austin Health, Victoria University and Royal Melbourne Hospital and is being conducted by researchers from these institutions. We aim to recruit 150 participants who have suffered a first stroke more than 6 months ago.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random), like tossing a coin.

You will be asked to undertake 15 sessions at Austin Health. The sessions are structured as follows:

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Session Number	Session Type	Duration (approximate)
1	Assessment – clinical only	90 minutes
2	Assessment – biomechanical only	90 minutes
3	Training	60 minutes
4	Training	60 minutes
5	Training	60 minutes
6	Training	60 minutes
7	Training	60 minutes
8	Training	60 minutes
9	Training	60 minutes
10	Training	60 minutes
11	Training	60 minutes
12	Training and Assessment – clinical & biomechanical	150 minutes
13	Assessment – clinical & biomechanical	90 minutes
14	Assessment – clinical & biomechanical	90 minutes
15	Assessment – clinical & biomechanical	90 minutes

Please wear shorts and <u>the same</u> pair of comfortable walking shoes for all sessions.

Sessions 1 and 2 (the first **assessments**) must be completed with at least one rest day in between. Your training sessions can then begin.

The ten **training** sessions will occur over a 5-6 week period, with at least one rest day between sessions.

Session 12 involves a training session, a rest period and then clinical and biomechanical assessments.

The final three **assessments** will take place 1 month, 3 months and 6 months after the completion of the **training** sessions.

At all sessions, you will walk on a treadmill for up to 10 minutes at a comfortable walking speed. Your level of fatigue will be assessed and rest breaks provided as necessary.

During the **clinical assessment sessions**, you will be asked to do some tests of walking, balance and leg strength, and you will be asked some questions about your risk of falls. These tests are routinely done by physiotherapists with people who have had a stroke. Session 1 will involve clinical assessment and some treadmill practice.

During the **biomechanical assessments**, you will be asked to walk on the treadmill for up to 10 minutes with some lightweight markers attached to your foot, lower limb and pelvis. These are used to track the movement of your feet and lower limbs and allow us to analyse your walking.

For the **training sessions**, you will be randomly allocated into Group A, who will receive treadmill training (treadmill and no visual feedback), or Group B, who will receive treadmill training plus feedback (treadmill with visual feedback).

Group A (Treadmill with no visual feedback): You will walk for up to 10 minutes on a treadmill at a self-selected speed.

Group B (Treadmill with visual feedback): You will walk for up to 10 minutes on a treadmill at a self-selected speed. While you are walking, you will be given 'biofeedback training'. You will be asked to maintain your toe position within two horizontal lines displayed on the screen, slightly higher than your preferred level. In the later sessions the duration of biofeedback will be gradually reduced.

During the sessions light weight markers will be fixed to your shoes, thigh and pelvis segments. The movement of these markers will be recorded by cameras, but your face will not be shown. You will also have lightweight measurement sensors attached to your feet to record movement of your feet and thin shoe inserts to measure pressure through the feet. These markers and sensors should not change the way you walk.

You will be given frequent rest periods, drinks and snacks as necessary throughout data collections. You will not be paid for your participation in this research, but you will be reimbursed for any of the travel costs (e.g., taxi fares, parking) that you incur as a result of participating in this research project. Interpreters will be provided if required. You may also be invited to participate in a focus group towards the end of the intervention period to determine your view on using feedback-based gait training intervention. These sessions will be recorded.

Falls data follow up: You will be asked to return a monthly falls calendar throughout the study (i.e., from enrolment to up to 12 months). Details about falls circumstances and consequences will also be collected. Falls calendars will be returned by post with telephone follow-up for any calendars that are not returned.

4 What do I have to do?

To participate in this study, you need to be over 18 years of age, have had a first stroke more than 6 months ago, able to walk 50m independently with or without a single point stick and finished your physiotherapy treatment. Participants who require an ankle foot orthosis, have problems with vision, or other neurological, orthopaedic, cardiac, respiratory or other medical condition that may impact on your ability to walk on a treadmill, are not eligible.

5 Other relevant information about the research project

This research is a collaboration between Austin Health, Royal Melbourne Hospital and Victoria University. One hundred and fifty participants will be recruited and attend either of the three locations for assessment and testing. Participants will be randomly assigned to two groups for training sessions – control group (receives no feedback) and the experimental group (feedback).

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish 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 project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Austin Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Participation in this study is offered to those who have completed their physiotherapy treatment. Any additional benefit of improving walking by participation in this study is not known or guaranteed. You can discuss your options with your treating health professional or local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include better foot clearance while you are walking. Following this data collection you will be provided with a report indicating your walking characteristics and ability to walk with a higher toe clearance. The results of this study, may lead to new methods of training walking in people who have had a stroke which may reduce falls in people with stroke.

9 What are the possible risks and disadvantages of taking part?

Possible risks, side effects and discomforts include a small risk of falls or injury, similar to the level of risk you are at during normal daily activities. You will wear a safety harness while you

are walking on the treadmill, which will prevent you from falling. The application and removal of the markers might be associated with some discomfort, similar to the discomfort of removing a bandaid. You may also experience feelings of fatigue due to the walking task.

The testing area will be kept private with access limited only to the researchers involved in this study. All data will be kept confidential and only the researchers will have access to the data files.

10 What will happen to my test samples?

No blood samples will be collected. Your limb position data will be recorded on the computer for further analysis of walking performance and the changes that occur with biofeedback training.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

You will not commence this project until you have stopped receiving regular physiotherapy. It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your doctor about any changes to these during your participation in the research.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the researchers would like to keep any data that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

We do not anticipate this study will be terminated before completion.

15 What happens when the research project ends?

On completion of the project, you will receive a report on your walking and your ability to increase your toe clearance.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law.

You will be assigned a code, and all data will be entered into the computer using this code. Data will be stored in REDCap, a computer application specifically designed for the safe storage of clinical research data. This data can only be accessed by the investigators. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about you may be obtained from your health records held at this, health service for the purposes of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your information will be stored for 7 years in accordance with HREC requirements for nondrug studies. Recorded limb position data will be stored for 7 years, and will be destroyed after this time.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the institution relevant to this Participant Information Sheet, Austin Health, Royal Melbourne Hospital and Victoria University, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

17 Complaints and compensation

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.

18 Who is organising and funding the research?

This research project is being conducted by Dr. Catherine Said. This research project is being funded by National Health and Medical Research Council.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Austin Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator on 03 9496 3697 or any of the following people:

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Clinical contact person

Name	Dr. Catherine Said
Position	Principal Investigator, Director Physiotherapy Research, Austin Health
Telephone	03 9496 3697
Email	cathy.said@austin.org.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Complaints Officer
Position	Austin Health Office for Research
Telephone	03 9496 4090 or 9496 3248
Email	ethics@austin.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Austin Health Human Research Ethics Committee
HREC Executive Officer	Dr Sianna Panagiotopoulos
Telephone	03 9496 4090
Email	ethics@austin.org.au

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Consent Form - *Adult providing own consent*

Title	Can Real-time Biofeedback of Foot Clearance Data be used to Assist with Gait Rehabilitation following Stroke?
Short Title	Biofeedback gait training in stroke patients
Protocol Number	1
Project Sponsor	NHMRC
Coordinating Principal Investigator/Principal Investigator	Prof Rezaul Begg (CPI) / Dr. Catherine Said (PI)
Associate Investigator(s)	Prof Farees Khan, Prof Mary Galea, Assoc Prof Pazit Levinger, Dr. Lisa James, Dr. Tony Sparrow
Location	Austin Health – Austin Repatriation Hospital

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Austin Health, Royal Melbourne Hospital and Victoria University concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care.

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

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

Note: All parties signing the consent section must date their own signature.

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Form for Withdrawal of Participation - *Adult providing own consent*

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Short Title	Biofeedback gait training in stroke patients
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Project Sponsor	NHMRC
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Location	Austin Health – Austin Repatriation Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Austin Health or Royal Melbourne Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/

Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.