Participant Information Sheet/Consent Form

The University of Sydney

Title	*Tailored intervention for reducing falls after stroke: the falls after stroke trial (FAST)*
Short Title	*Reducing falls after stroke: the FAST trial*
Protocol Number	2.0
Project Sponsor	NHMRC University of Sydney
Coordinating Principal Investigator/ Principal Investigator	*Professor Lindy Clemson* *Professor Catherine Dean* *Professor Louise Ada* *Dr Kate Scrivener*
Associate Investigator(s)	*Dr Elisabeth Preston*
Location	*Sydney and Canberra*

Part 1 What does participation involve?

1 Introduction

You are invited to take part in this research project, because you have been diagnosed with stroke and have been discharge from rehabilitation. The research project is testing a new rehabilitation approach called a home-based tailored approach to prevent falls after stroke.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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 have the tests and treatments 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 is about preventing falls. We aim to find out if a home-based tailored approach can help people like yourself. There are two treatment options: one is usual care which involves whatever your healthcare providers recommend. The other program is a tailored intervention consisting of habit-forming exercise and/or safety training. The habit-forming exercise is based on the integrated lifestyle approach (the LiFE program) that includes balance training which has been shown to be beneficial in preventing falls in older Australians without stroke and is used in many rehabilitation and community health settings across the world. However it has not been tested with people who fall after a stroke. The safety intervention will focus on environmental adaptations to reduce fall hazard and protective behaviours to reduce risk. Therefore, this is considered to be an experimental treatment for balance/safety training and fall prevention for stroke. This means that it must be tested to see if it is an effective treatment. The program is taught to you in your home by a trained health professional. We provide training, support and follow up for your exercise program.

This research has been initiated by the study doctors, Professor Clemson and Professor Catherine Dean, and pilot work was funded Macquarie University. We now have funds from National Health and Medical Research Council for the large study.

3 What does participation in this research involve?

If you are willing to take part in the project, 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). You have equal chance of being in either of the two groups; the usual care group or the home-based tailored group.

If you are allocated to the home-based tailored group, we will provide personal training by a physiotherapist or an occupational therapist who will give support and follow-up over the 6 months of the project. The research therapist will visit you at home for training and follow up for 10 visits. We will also telephone you on a regular basis - at least every two months. We provide a booklet about your exercise program which contains photos and instructions of how to do your exercise program. We shall be asking you to record your practice using a weekly log to monitor your adherence to the exercise program.

If you agree to participate in this study, and BEFORE we give you your exercise program, we will ask you questions about how much physical activity you do, your confidence in doing different daily activities, what kinds of social activities you engage in, your gait and balance, and your medical history. We shall be asking you to keep a monthly calendar record, marked off daily, showing us whether or not you have had a fall and your exercises to tell us how much and how often you have exercised.

In addition, we will test your walking speed, balance and measure the distance you can walk in 6 minutes.

All of these tests will be done when we first see you at your home. Some of these will be repeated at 6 months and then all of them again at 12 months. They will take about two hours to complete. You can rest at any time and take longer if you wish. Feel free to have a friend or family member to be present if you feel this may make you more comfortable.

All assessments are undertaken at your home by a trained research assistant who is also a health professional. This research assistant will not know which group you were in and we would ask that you do not tell them. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or research assistants jumping to conclusions. We may also invite you to participate in an interview for you to tell us what you thought about the intervention and any suggestions you may have to improve the intervention. You are free to decline the interview opportunity.

Your research therapist will be allocated to you after the first assessment is completed. They will give you a ring and arrange to come and visit and teach you your exercise program.

There are no additional costs associated with participating in this research project, nor will you be paid. All tests and exercise therapies required as part of the research project will be provided to you free of charge.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

During the study, if you are in the home-based tailored exercise program you will be provided with personal training by a physiotherapist and/or an occupational therapist who will give support and follow-up over the 6 months of the project. The program will be progressed in small, incremental steps, and are designed to increase your strength and reduce your likelihood of falling. It will be your responsibility to follow the instructions of your study therapist and complete your exercise program in your own home according to the instructions that your therapist will give you.

For both groups, there are no lifestyle restrictions to taking part in this study.

5 Other relevant information about the research project

We have secured funding from the National Health and Medical Council, we will recruit 370 adults in Sydney and Canberra and involve researchers from The University of Sydney and Macquarie University (The University of Canberra, La Trobe University as well as international researchers in the UK and USA.

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 The University of Sydney.

7 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 receiving a tailored exercise program and an

opportunity to have a rehabilitation therapist visit your own home to adjust these exercises to suit your home environment.

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

If you are in the home-based tailored exercise group you may develop minor muscle soreness. It is normal to feel some muscle soreness from training. There is a small risk of injury during physical function tests and exercise training sessions. However, this is very rare during the kind of strength, balance, and flexibility testing proposed here. You will be closely supervised by a trained health professional during all tests and on a number of occasions at home. With any exercise, there is a very remote chance of chest pain or heart attack, abnormal blood pressure, or irregular heart beat during training, but this is very unlikely to occur during the kind of balance, strength and flexibility training which we have proposed.

9 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, the Chief Investigator will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the Chief Investigator may be able to make a referral to a community health service for you to continue a falls prevention program. If you decide to continue in the research project you will be asked to sign an updated consent form.

10 Can the participant have other treatments during this research project?

Whilst you are participating in this research project, you are able to continue to take all of the medications you have been taking for your condition or for other reasons. It is important to tell your research assistant and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

11 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 special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by The University of Sydney and Macquarie University to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

12 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The treatment being shown not to be effective
- The treatment being shown to work and not need further testing

13 What happens when the research project ends?

The two interventions will not be available after the research finishes. At your completion, the study staff will speak with you and if you wish, can make a referral to Community Health at no cost to you.

As a participant, you may wish to find out the results of this project. We expect that we will finish this study in 2023, and that at this time, we will mail a one-page summary of the findings to all interested participants.

Part 2 How is the research project being conducted?

14 What will happen to information about the participant?

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. We do this by giving all your data a code, and we do not write your name on these forms. When we have finished this study, all the data will be stored in a locked office at The University of Sydney, where only the named research team members will have access to this information. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose 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 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 relevant authorities, the institution relevant to this Participant Information Sheet, The University of Sydney, 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.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums, including publication in a medical journal and conference presentations. In any publication and/or presentation, information will be provided in such a way that you cannot be identified; only group data are presented.

Information about your participation in this research project may be recorded in your health records.

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.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

15 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.

16 Who is organising and funding the research?

This research project is being conducted by a team of researchers from The University of Sydney and Macquarie University. The Chief Investigators are Professors Clemson and Ada

from The University of Sydney and Professor Catherine Dean and Dr Scrivener from Macquarie University.

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

17 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 Macquarie University.

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.

Approval has been given by Macquarie University, who are responsible for supervising the standard of care where this project is taking place.

18 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 study investigator:

FAST trial coordinators

Name	Dr Stefanie Mikolaizak and Mrs Sally Day
Position	Trial coordinators
Telephone	02 9351 9989
Email	FAST.study@sydney.edu.au

Clinical contact person:-_Sydney

Name	Dr Kate Scrivener
Position	Chief Investigator
Telephone	02 9850 6620
Email	Kate.scrivener@mq.edu.au

Canberra

Name	Dr Elisabeth Preston
Position	Associate-Investigator
Telephone	(02) 6201 5749
Email	Elisabeth.Preston@canberra.edu.au

Consent Form – *Adult providing own consent*

Title	*Tailored intervention for reducing falls after stroke: the falls after stroke trial (FAST)*
Short Title	*Reducing falls after stroke: the FAST trial*
Protocol Number	2.0
Project Sponsor	*NHMRC_The University of Sydney*
Coordinating Principal Investigator/ Principal Investigator	*Professor Lindy Clemson/ Prof Catherine Dean/ / Prof Louise Ada/ Dr Kate Scrivener*
Associate Investigator(s)	*Dr Elisabeth Preston*
Location	*Sydney and Canberra*

Declaration by Person Responsible

I have read the Participant Information Sheet 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 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 the participant at any time during the research project without affecting my future health care. I understand that I will be given a signed copy of this document to keep.

I give permission for the participant's doctors, other health professionals, hospitals or laboratories to release information to The University of Sydney concerning my disease and treatment for the purposes of this research project. I understand that such information will remain confidential.

Name of Participant (please print) _____

Signature of Person Responsible _____ Date _____

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 person responsible has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

PARTICIPANT'S COPY

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I have read the Participant Information Sheet someone has read it to me in a language that I understand.

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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 the participant at any time during the research project without affecting my future health care. I understand that I will be given a signed copy of this document to keep.

I give permission for the participant's doctors, other health professionals, hospitals or laboratories to release information to Macquarie University concerning my disease and treatment for the purposes of this research project. I understand that such information will remain confidential.

Name of Participant (please print) _____

Signature of Person Responsible _____ Date _____

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 person responsible has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

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

INVESTIGATOR'S COPY

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

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Coordinating Principal Investigator/ Principal Investigator	*Professor Lindy Clemson/ Professor Catherine Dean/ Professor Louise Ada / Dr Kate Scrivener*
Associate Investigator(s)	*Dr Elisabeth Preston*
Location	*Sydney*

Declaration by Person Responsible

I wish to withdraw from taking part in the above research project and understand that such withdrawal will not affect my routine treatment, relationship with those treating me or my relationship with Macquarie University.

Name of Participant (please print)

Signature of Person Responsible _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Staff/Senior Researcher will need to provide a description of the circumstances below.

Name of Study Doctor/
Senior Researcher (please print) _____

Signature _____ Date _____

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