Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Fit 4 Me After Stroke: A Phase I/IIA Clinical Trial
Short Title	Fit 4 Me After Stroke
Project Number	2022.133
Coordinating Principal Investigator (CPI):	Dr Natalie Fini
Site Principal Investigator (PI):	Dr Natalie Fini
Site Associate Investigators	Professor Julie Bernhardt Associate Professor Cathy Said Professor Leonid Churilov Dr Kate Hayward Professor Gavin Williams Dr Liam Johnson Ms Emily Ramage Dr Chris Tzefronis Mr Paul Fink Ms Erin Bicknell Professor Jill Francis Professor Coralie English
Location	The University of Melbourne

Part 1 What does my participation involve?

1 Introduction

This research project will test the feasibility and potential benefit of a physical activity program “Fit 4 Me After Stroke” for people with stroke. You are invited to take part in this research project because you have had a stroke within the past 6 months.

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

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. 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 form. 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 the Consent Form to keep.

2 What is the purpose of this research?

The purpose of this research project is to find out if a **physical activity program** is **feasible** and **beneficia**l for people who have had a **stroke**.

People who have suffered a stroke are at a higher risk of future health problems, including having another stroke. Being physically active is important for preventing stroke and other cardiovascular (heart) diseases. It can be challenging for many stroke survivors to be physically active due to the effects of having a stroke such as muscle weakness, poor balance, and poor fitness. Treatments are needed to help stroke survivors to start and sustain regular physical activity.

This research aims to test a personalised physical activity program: "Fit 4 Me After Stroke" that our team has designed together with stroke survivors, their carers and stroke clinicians. The aim is to **determine how much exercise** is **acceptable** and also **effective at improving health**. This will ultimately reduce risk of future stroke and heart disease.

This study will investigate the Fit 4 Me After Stroke program which commences within six months of having a stroke. It has been designed to meet your individual needs.

This study will help to guide the development of future research trials and increase stroke survivors' participation in exercise and physical activity.

This research has been initiated by the Principal Investigator (Dr Natalie Fini) through the physiotherapy department at the University of Melbourne. It is being partly funded by a Stroke Foundation grant.

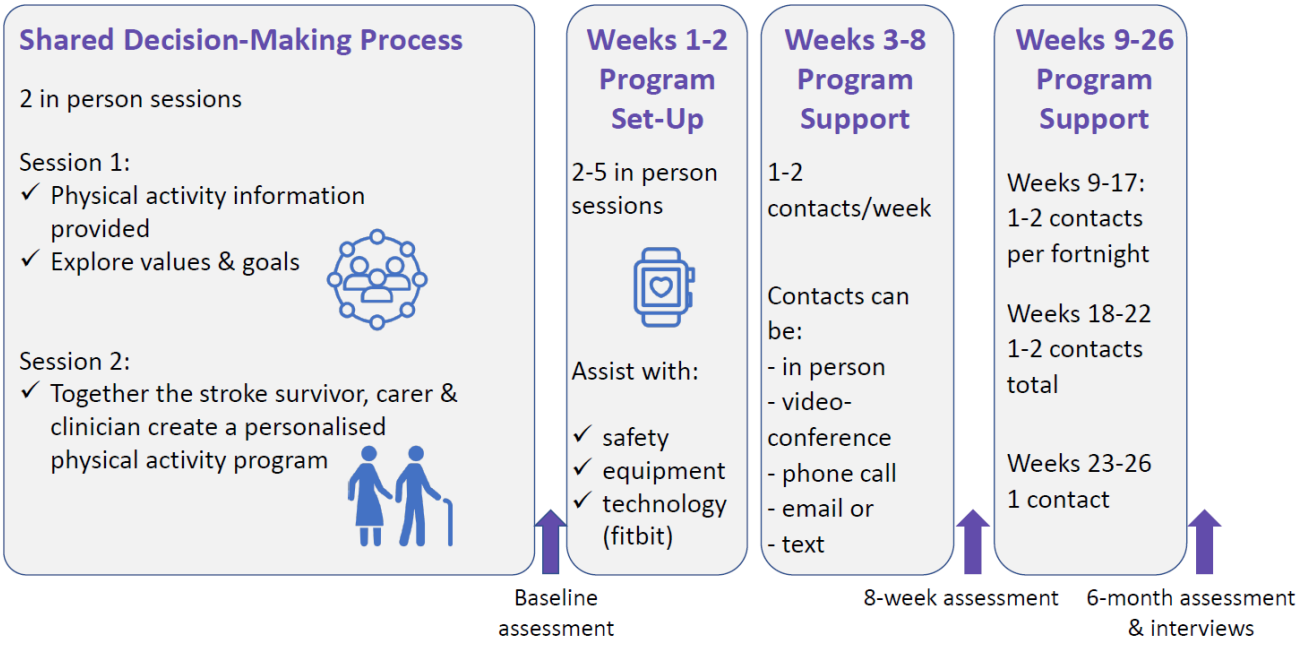
3 What does participation in this research involve / What do I have to do?

The duration of the study is **six months** and participants must commence the program within six months of having a stroke.

You will be asked to participate in the Fit 4 Me After Stroke physical activity program for 50-150 minutes per week doing your chosen type of activity at an intensity level for your individualised needs. The 50-150 minutes of physical activity can be spread throughout the week in as many sessions as suits you best.

Participation in this research study will involve the following:

Figure 1 – Fit 4 Me After Stroke Study



<u>Shared Decision Making Process</u>
2 sessions with a trial therapist (physiotherapist or exercise physiologist) at a mutually agreed location (can be your home) to design your own personalised physical activity program using **shared decision-making**. You are welcome to invite a family member, friend or carer to participate in these sessions.

- You will be given a weekly target of how much physical activity you will do and how intense that activity will be.
- You will be provided with a copy of your physical activity goals, plan and targets.

<u>A baseline assessment session</u> with a second therapist who will take you through several tests and questionnaires. This will be completed at a mutually agreed location (can be your home). These tests will measure your blood pressure, walking ability and speed, physical activity, mood, confidence to exercise and fatigue and should take less than1 hour to complete.

- You will be provided a smartwatch (i.e., a Fitbit) to wear to monitor your physical activity, along with instructions on how to use it.
- You will also be asked to wear a second activity monitor device (an actigraph) that measures your activity intensity. You will be asked to wear this for three separate 1-week periods over the first two months of the program

Weeks 1-2 Fit 4 Me After Stroke Program Set Up
Physical activity program set-up: the trial therapist will meet you at the location of your chosen physical activity (e.g., the park, home, gym) to run you through your physical activity program. You will also be provided with an activity diary and shown how to complete it.

Weeks 3-8 Fit 4 Me After Stroke Program Support
Over the following 6 weeks you will receive support to continue with your physical activity program. (See Figure 1 – support will be delivered in the way you would like to receive it – in person, via video conference, phone, email or text).

Second assessment session at 8-weeks
This will involve the same assessments and questionnaires as the first assessment session and will be completed at a mutually agreed location (can be your home).

Weeks 9-26 Ongoing support: (See Figure 1 – support will be delivered in the way you would like to receive it – in person, via video conference, phone, email or text).

Final assessment session at 6 months
This will occur at the end of the program and it will involve doing the same assessments and questionnaires as previous and will be completed at a mutually agreed location (can be your home).

Interview: you may be asked to participate in a 30 – 60 minute interview within three weeks of completing the study. This interview will be conducted via videoconference or phone call and will ask about your experience of participating in the Fit 4 Me After Stroke program, including your perceived benefits and challenges. We will ask your permission to record the interview.

- Within three weeks of your interview, we will provide you with a summary of the interview (via email or post) so that you will have the opportunity to review your responses and share any further thoughts.
- For writing out (transcribing) the audio-recorded interviews, we may make use of the services of Otter.ai, a company that uses automated software rather than human transcribers. Any identifiable data will be edited out of the recording prior to sending to Otter.ai. Information captured in your interview recording will be subject to Otter.ai's Terms of Service (https://blog.otter.ai/terms-of-service/) and Privacy Policy (https://otter.ai/privacy). Otter.ai stores and processes information in the United States of America. Your recording will be deleted from Otter.ai's platform once results have been fully analysed.

During the time you are participating in this study you can continue to receive any usual care rehabilitation you are doing. We will ask you how much you are doing. There are no restrictions on your usual activities, diet or medications. We will ask you to try your best to stick to your physical activity targets.

The research will be monitored by the research team at the University of Melbourne. There are no costs associated with participating in this research project, nor will you be paid. However, if your chosen type of physical activity includes a cost (e.g., a gym membership), you will be asked to pay for this as the research aims to encourage physical activity that will continue after the research has ended.

You will need medical clearance to participate in this study. You can get this from your local doctor, neurologist, cardiologist or rehabilitation specialist. The research team may be able to help you to make an appointment if you are unable to do this yourself. We will inform your local doctor of your participation in this research project. We will also provide them with a copy of your physical activity plan. We may refer you on to them to follow up on any assessment findings that our outside of normal ranges (e.g., blood pressure or mood).

4 Other relevant information about the research project

This research aims to find out how much physical activity is best - both for your health and what you can reasonably manage. The Fit 4 Me After Stroke program was co-designed with the research team, stroke survivors, carers and clinicians.
This is a multi-site project being conducted through the University of Melbourne, Royal Melbourne Hospital, Alfred Health, Western Health and Epworth Healthcare.

5 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 a signed copy of this Participant Information and Consent Form 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 or your relationship with those treating you.

6 What are the alternatives to participation?

You do not have to take part in this research project. You will receive any usual care you receive regardless of whether or not you are in the project.

7 What are the possible benefits of taking part?

We know **physical activity is good for you**, and we are trying to work out **how much exercise is best**, and hope to improve your physical activity levels, mobility, blood pressure, mood and overall health. However, you may not directly benefit from this research, as we have not yet tested this specific intervention and do not know whether it is effective.

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

International guidelines recommend exercise and physical activity for people after stroke, but we're not sure how much is best. **Physical activity is safe** but as this is a study, we will monitor you for any symptoms you may experience. The assessments and Fit 4 Me After Stroke program are unlikely to cause any physical injury or psychological distress.

You will need to provide medical clearance to participate in the study and the individuals who will work with you throughout the study are experienced physiotherapists or exercise physiologists. You may find the physical activity program tiring or you may experience some mild muscle soreness in the day following activity. If you feel mild symptoms (e.g., muscle soreness) during exercise, the physiotherapist/exercise physiologist will modify the exercise and give appropriate advice on management. While strategies to minimise falls while exercising will be in place, there is a risk that you may fall. If you report a significant injury associated with exercise, you will be referred to your local doctor or other medical practitioner for review. Safety procedures will be followed if an incident occurs during a session supervised by a research team member. A home/community safety assessment will be conducted prior to home/community visits in the interest of participant and staff safety.

If you become upset or distressed as a result of your participation in the research, the researchers will be able to arrange for counselling or other appropriate support.

9 Can I have other treatments during this research project?

You can have any other treatment you wish, including medications, but it is important to tell us about these.

10 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. You can do this by completing the “Withdrawal of Consent” form attached below as part of this information package. 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 research team 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 research team up 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.

11 Could this research project be stopped unexpectedly?

Although it is unlikely, if this project is terminated before its completion, we will notify you.

12 What happens when the research project ends?

After your involvement in the research project is over, you will continue to receive your usual care as directed by your therapy team if you have one, or local doctor. You will need to return the Fitbit smartwatch once you have finished participating in the study. The results from the project will be published in relevant medical journals and presented at relevant conferences. No individual personal information will be published. You will be offered a one page summary of the overall research findings once the study is completed.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form, you agree to the research team 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**. Data will be coded using numbers so it will be de-identified. This includes audio-visual recordings if you participate in the interview, which will be typed out by a third party who will not have your details. A password protected online REDCap database, licensed to the University of Melbourne will be set up to store the coded data and recordings. This database will be stored on the University of Melbourne server. Only research team members will have access to the online database. The data obtained in hard copies will be stored in a locked cabinet which is only accessible by the research team. 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.

By signing the consent form you agree to the study team accessing information about you from your health records held at health services if they are relevant to your participation in this research.

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. This review may be done by the institution relevant to this Participant Information Sheet, The Royal Melbourne Hospital, or as required by law. By signing the Consent Form, you authorise release of, or

access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

Only summary data will be published, and alternative names will be used for presentation of the interview data. Five years after the last research publication all information videos and photos will be disposed of in a confidential manner with paper files being shredded and electronic files, photos and videos deleted.

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.

14 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the research 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.

15 Who is organising and funding the research?

This research project is being led by Dr Natalie Fini. The research project is being partially funded by a Stroke Foundation Grant awarded to Dr Fini. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than ordinary wages).

16 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 The Royal Melbourne Hospital. 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.

17 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 about this project or if you have any problems related to this project you can contact the principal researcher:

Coordinating Principal Researcher (CPI)

Name	Dr Natalie Fini
Position	Physiotherapist / Principal Researcher
Telephone	0401 303 749
Email	natalie,fini@unimelb.edu.au

Site Principal Researcher (PI)

Name	Dr Natalie Fini
Position	Physiotherapist / Principal Researcher
Telephone	0401 303 749
Email	natalie,fini@unimelb.edu.au

For matters relating to research at the site at which you are participating or ff 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 approving this research and HREC Executive Officer details

Reviewing HREC name	The Royal Melbourne Hospital HREC
HREC Executive Officer	Manager HREC
Telephone	(03) 9342 8530
Email	Research@mh.org.au

Local HREC Office contact (Research Governance Officer) & Complaints contact person

Position	Manager
Telephone	+61 3 8344 2073
Email	HumanEthics-complaints@unimelb.edu.au

Consent Form – *Adult providing own consent*

Title	Fit 4 Me After Stroke: A Phase I/IIA Clinical Trial
Short Title	Fit 4 Me After Stroke
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Coordinating Principal Investigator	Dr Natalie Fini
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Location	The University of Melbourne

Consent Agreement

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 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.

I am aware that the interview audio recording may be provided to third-party service provider Otter.ai for transcription. I acknowledge that information captured in the interview recording will be subject to Otter.ai's Terms of Service and Privacy Policy, and information will be stored and processed by Otter.ai in the United States of America. I acknowledge that my recording will be deleted from Otter.ai's platform once results have been fully analysed.

☐ I consent to having the follow-up interview recorded (audio-visually)

☐ I agree to the interview transcription through a third-party provider

☐ I agree to the researchers contacting me after this research to see if I'd like to be involved in further follow-up for this project or other stroke research projects.

I would like a summary of the results of this study ☐ No ☐ Yes
My preferred method of communication of the results is: ☐ Email ☐ Post
My contact details are:_____

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form
Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

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.

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

Title	Fit 4 Me After Stroke: A Phase I/IIA Clinical Trial
Short Title	Fit 4 Me After Stroke
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Coordinating Principal Investigator	Dr Natalie Fini
Site Principal Investigator	Dr Natalie Fini
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Location	The University of Melbourne

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 The Royal Melbourne Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

Circumstances:

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.

THE UNIVERSITY OF MELBOURNE

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.