Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

The University of Melbourne

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 **Participant Information Sheet** tells you about the research project.

You might want to talk about it with a relative, friend or your local doctor before you decide to take part.

If you decide you want to take part in the research project, you will be asked to sign the consent form.

2 What is the research about?

Being physically active is important for:

-  **reducing the risk** of **another stroke** and,
-  other health problems like **heart disease**.

This research will test a **personalised physical activity program** called “Fit 4 Me After Stroke”.

The aim of this research is to find out **how much**:

 **exercise** is **acceptable** and,

 works to improve **health** after stroke.

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Local Aphasia Friendly PICF V1 dated 17.06.22

3 What do I have to do?

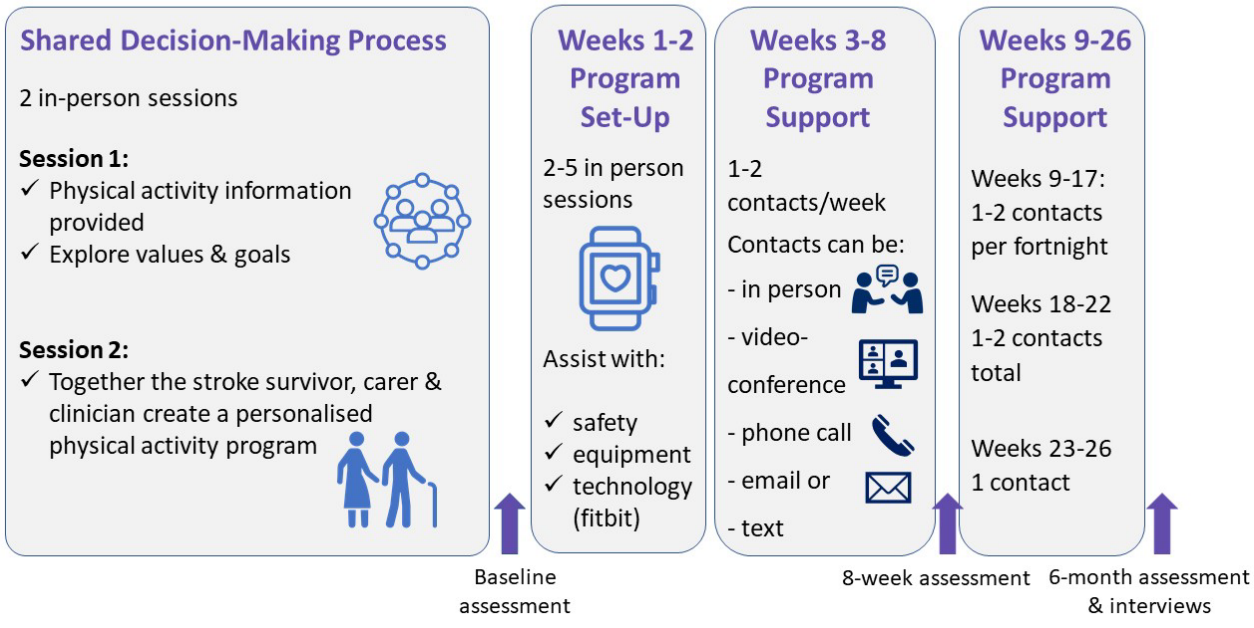
You will be asked to participate in the **Fit 4 Me After Stroke physical activity program** for:

- **50-150 minutes per week** at your target intensity level spread throughout the week.

- a **6-month program**.

Participation in this research study will involve the following:

Figure 1 – Fit 4 Me After Stroke Study



Shared decision-making Process

2 sessions with a therapist to design your own personalised physical activity program using **shared decision-making**.

- 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.

Baseline, 8-week and 6-month assessment

- In each assessment session, a therapist will take you through **several tests and questionnaires** which should take **less than 1 hour to complete**.
- These tests will measure your:
  -  blood pressure
  -  walking ability, physical activity and confidence to exercise
  -  mood
  -  fatigue
-  We will ask you to monitor your physical activity by:
  - Wearing a **smartwatch (i.e., a Fitbit)** to wear daily to monitor throughout the trial
  - A **second activity monitor device** (an actigraph) to wear on 5 separate 1-week occasions over the 6 months. The actigraph measures your activity intensity.
- The assessment sessions will take place at your **home** or an agreed location.

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Week 1-2 Program set-up

The trial therapist will meet you at the location of your chosen physical activity (e.g., the park, home) to run you through your physical activity program.

You will also be given an **activity diary**.

Interview

You may be asked to participate in a **30 - 60-minute interview** within three weeks of completing the study.

This will be conducted via **videoconference** or **phone call.**

We will ask about your experience of participating in the program.

We will ask your permission to **record** the interview.

- Within 3 weeks of your interview, we will provide you with a **summary of the interview** (via email or post).

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4 Other information about the research project

- During this study, you can continue to receive all of your usual care/ rehabilitation (we will ask you how much you are doing).
- There are **no restrictions** on:
  -  your usual **activities**
  -  **diet**
  -  **medications**.

There are **no costs** associated with participating in this research project. You will not 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 doctor or specialist.

You will need to **return** the Fitbit smartwatch at the end of the study.

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 then change your mind, you can **withdraw** from the project **at any stage**.
- Your decision **will not affect** any routine treatment you are having.

6 What are the alternatives to participation?

You **do not** have to take part in this research project.
You will receive your routine treatment regardless of whether or not you are in the project.

7 What are the possible benefits of taking part?

You may not directly benefit from this research.

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
- overall health.
-

8 What are the possible risks of taking part?

Physical activity is safe but 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.

If you feel mild symptoms during exercise (e.g., muscle soreness), the physiotherapist will **modify the exercise** and give appropriate advice on how to manage it. Therapists will screen all locations and exercises for safety and **safety procedures** will be followed at all times.

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 **tell** a member of the research team **before** you withdraw.

If you do withdraw your consent during the research project, the research team **will not** collect extra personal information from you, although personal information **already collected** will be **kept** to ensure that the results of the research project:

- can be measured properly
- comply with law.

Data collected by the research team up to the time you withdraw will be part of the research project results.
If you **do not** want the research team 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 it is finished, we will tell you.

12 What happens when the research project ends?

After your involvement in the research project is over, you will continue to receive your routine treatment as directed by your therapy team or local doctor.
The **results** from the project will be published in:


medical journals and presented at conferences.


No individual personal information will be published.

You will be offered a one-page summary of the research findings after the study is completed.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

Any information from this research project will remain **confidential**.

- Data will be stored on a REDCap Database, licensed to the University of Melbourne and stored on the University's server.
- We may use the services of Otter.ai to transcribe audio recordings of the interviews. Information captured in the 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 store stores and processes information in the United States of America. Your recording will be deleted from Otter.ai's platform once we have finished analysing the results.

Only research team members will have access to the information.

Your information will only be used for this research project, except if required by law.

Information about you may be taken from your health records held at this and other health services for the purpose of this research.

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.

You have the right to request access to your information collected and stored by the research team.

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. You will be assisted with arranging appropriate medical treatment.

15 Who is organising and funding the research?

This research project is being led by the coordinating Principal Investigator - Dr Natalie Fini.

The research project is being partially funded by a Stroke Foundation Grant awarded to Dr Fini.

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.

17 Further information and who to contact

If you:

- want any further information about this project
- have any medical problems which may be related to your involvement in the project (for example, any side effects)

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 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 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

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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 theUnited 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*

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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.

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.