Booklet

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ENAbLE
Physical activity & diet trial for secondary prevention of stroke

PATIENT LABEL

ENAbLE - pilot

A physical activity and diet trial to reduce the risk of second stroke (pilot)

Principal Researcher: Associate Professor Coralie English

PARTICIPANT INFORMATION STATEMENT

If you would like help in understanding this information sheet or need an interpreter please contact: Stroke Research Register, Hunter on (02) 4042 0093 or enable-pilot@newcastle.edu.au . We can provide access to a professional, confidential and free health interpreter service.

What is the research about?

We know that exercise and a good diet can reduce the risk of having another stroke and improve your overall health and well-being. We want to test whether we can provide exercise and diet programs to people in their home that are delivered over the internet using a computer device such as an laptop, iPad, or tablet. This is called telehealth and will include video-calls.

What will I be asked to do?

If you agree to participate, you will be asked to visit your local GP and obtain medical clearance to participate in the study. We will send you a form to take to your GP, and they will return it to us. We will ask them to let us know if you have any medical conditions that would make it unsafe for you to participate in the study provide some information about your medical history.

You will then be randomly allocated (like tossing a coin) to one of the following four groups:

- **Advice and education group.** You will receive advice and education about exercise and diet (including written pamphlets and links to online information).
- **Exercise program group.** You will receive an exercise program designed to suit your level of ability, supervised by a qualified physiotherapist or exercise physiologist with experience in stroke.

- **Diet counselling group.** You will receive specialised diet counselling and support from a qualified dietitian.
- **Exercise plus dietary counselling group.** You will receive both the exercise program and specialised diet support

If you are in the exercise program group we will ask you to:

For the first 3 months

- Complete 2 supervised exercise sessions each week in your own home. Exercises could include marching or stepping on the spot, moving from sitting to standing, lifting small weights (such as tins of food) or walking. We aim to include 30 minutes of exercise in each session. We may recommend that you have someone with you while you exercise. Exercise sessions will be supervised by video-calls (telehealth) on your laptop or tablet. We can loan you a tablet device if you need one.
- Follow an exercise plan on the other days of the week. We will work with you to develop an exercise plan that suits you.

For the second 3 months

- Continue with your exercise plan on your own. We will contact you each week to provide advice and encouragement.

You will be provided with a small device to measure your heart rate during exercise (a pulse oximeter) as well as an option to track your activity over the week (e.g. a FitBit) and we will show you how to use these (see pictures below). You will tell us your heart rate at the end of each exercise, and/or you can choose whether you want to upload this to a smart phone and allow us to view this information.

1. Pulse Oximeter

2. FitBit

If you are in the diet counselling and support group we will ask you to:

- Follow a modified Mediterranean-style diet (predominantly plant–based, using olive oil as the main culinary fat, high in fibre and limited in processed foods).
- We will work with you to develop a diet plan that suits you. We will send you some samples of different foods to try, menu plans and shopping lists.
- We will contact you using video-calls on your laptop or tablet to provide individual diet counselling and advice.
- There will be 10 sessions each lasting 30-60 minutes (7 in the first 3 months, 3 in the second 3 months).
- We will also send you text messages for support.

If you are in Exercise plus dietary counselling group we will ask you to do the activities for both the exercise program and the diet counselling and support groups. We will contact you using video-calls 6 times in the first fortnight, then 4-5 times per fortnight for the remainder of the first 3 months, then approximately 2 to 3 times a fortnight in the next 3 months.

All participants in the diet and exercise programs will have the option of receiving session reminders and summaries of programs by your choice of delivery methods (e.g. by mail, text messages, email, or post, or by verbal or visual reminders, or via web resources) and the option of attending peer support through group teleconference or via a closed Facebook group.

So we can measure if the program works, we will ask you to do the following before you start the program, and again after 3, 6 and 12 months of starting the program.

1. Answer some questions about your stroke, your medications, your health, how much exercise you do and your diet. This will be conducted by 2 video-calls lasting 1-2 hours. We will help you to connect to the video-call by contacting you by phone if necessary.
2. Take regular blood pressure measures, twice each day for 1 week at home (we will send you a home blood pressure monitor and show you how to use it). If

you agree your blood pressure and heart rate can be recorded on a device (e.g. a smart phone or tablet) and you can choose to share these measures with the research team. If you don't agree we will ask you to tell us your blood pressure and heart-rate during the video-calls.

3. Wear an activity monitor on your thigh for 1 week to measure how active you are (we will send the monitor and show you how to use it).

4. We might also ask you to do an interview with one of our research team about your experience in being involved in the study.

1. Blood pressure monitor

(take blood pressure twice each morning and night for 7 days at the start, at 3 months, 6 months and at 12 months).

2. Physical Activity Monitor

(wear for 7- days at the start, at 3 months, 6 months and at 12 months)

Who can participate?

You are suitable to participate if you:

- are aged over 18 years
- have had a stroke or TIA in the last 10 years, you can begin this study as early as 3 months after your stroke or TIA
- are able to walk at least short distances without someone helping you

- have an internet connection and either a laptop computer or tablet device at home (we may be able to provide one if you don't)
- have medical clearance from your doctor to exercise (we will help arrange this)
- are living in Australia

Where is the research being done?

This is study is conducted within the University of Newcastle, NSW and Western Health, Victoria. **The entire trial, including the exercise and diet programs and the assessments, will happen in your own home. We will use a video-link so that a qualified person can support and instruct you (we call this 'telehealth' – video-conferencing on a computer or tablet device).**

What choice do you have?

Participation in this study is entirely voluntary. You do not have to take part in this study. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

What are the risks and benefits of participating?

If you are in the exercise group, there is a small **risk** of having a health event or falling over. This risk will be minimised by getting medical clearance from your usual doctor (GP). To ensure the program is carried out safely we may recommend or require that someone is with you while you are undertaking your exercise sessions, and that you also provide us with an emergency contact person (someone who lives close by). If an emergency arises we will call 000 and direct emergency services to your address, and also call your emergency contact person. Doing regular exercise and eating a healthy diet should **improve your general health** as well as reduce your risk of future strokes.

How will your privacy be protected?

All the information collected from you for the study will be treated confidentially, and only the researchers involved will have access to it. The study results may be presented at a conference or in a scientific publication, but individual participants will

not be identifiable. All personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

If you decide to withdraw from the study, with your permission we will use data already collected from you in our study analyses. However, if you direct us to, we will destroy all data relating to you.

We may use data collected in future studies or analyses. We may contact you in the future for permission to collect more data on the long-term benefit of the study.

All personal information will be accessed, used and stored for a minimum of 15 years in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002. You may request a copy of all personal information collected during the study.

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For **help, or more information** you may contact the researchers directly:

Professor Coralie English **(02) 4913 8102** **email :** coralie.english@newcastle.edu.au	Stroke Research Register (Hunter) **(02) 4042 0093** **email :** strokeregister@hmri.org.au

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, 2019/ETH11533

If you have concerns about your rights as a participant, or a complaint about the manner in which the research is conducted**,** you can speak to the research team. **Or, if an independent person is preferred, you may contact the ethics coordinator:**

Hunter New England Health

Dr Nicole Gerrand

✉ Hunter New England Human Research Ethics Committee
Hunter New England Local Health District
Locked Bag 1
New Lambton NSW 2305

Phone (02) 49214950**email:** HNELHD-HREC@health.nsw.gov.auFor matters relating to research at the site at which you are participating, and 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 the details of the local site complaints person are: