**PARTICIPANT INFORMATION AND CONSENT FORM (PICF)**

**Project Title:**

Post Ischaemic Stroke Cardiovascular Exercise Study –

Zoom Delivered Intervention Against Cognitive Decline (PISCES-ZODIAC)

**Principal Researchers:** Professor Amy Brodtmann,

Dr PHILIP CHOI (Eastern Health), Professor TISSA WIJERATNE (Western Health), Professor Gavin WILLIAMS (Epworth Health)

**Associate Researchers:** Dr Jean Sebastien Teoh, Ms Kim Adkins, Ms Ruwayda Haibe, Ms Elizabeth McInerney

**Location**: [Insert name of site]

Part 1 – What does my participation involve?

1. Introduction

You are invited to take part in this research project because you have experienced an ischaemic stroke in the past 2 months. In this research project, we are aiming to examine the beneficial effects of exercise after stroke. Specifically, we are looking at whether home-based exercise can prevent some damaging brain changes after stroke, and whether any such changes in brain volume or brain function are related to cardiovascular function (such as more strokes, blood pressure, or general fitness).

This Participant Information and Consent Form tells you about the research project. It explains the 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 healthcare worker.

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.

## What is the purpose of this research project?

The health of the body’s blood vessel system (vascular system) is the greatest determinant of brain structure and function late in life. Ischaemic strokes (when blood is not delivered to parts of the brain) are a result of a cerebrovascular disease (i.e., a medical condition impacting on the wellbeing of the blood supply to the brain). Using brain imaging techniques, we have found that after a stroke there is an increased rate of brain structure changes, particularly brain volume loss (atrophy). In addition, cognitive function (i.e., your thinking capacity) can decline and may be a sign of a dementia (e.g., worse memory, concentration, thinking). All these changes are in comparison to someone who has not had a stroke before. However, not everyone who has a stroke experiences brain changes or cognitive dementia. The major risk factors that have emerged for post-stroke brain atrophy and cognitive decline are recurrent stroke, hypertension, and low rates of physical activity.

This project is interested in understanding the impact of exercise on brain recovery and cardiovascular well-being after a stroke. After being introduced to an 8-week home-based exercise programme at 2 months post-stroke, we will monitor changes as a result of the exercise at 4 months post-stroke, and then at 12 months (1 year) post-stroke. The specific changes we intend to monitor include brain volume and connections using brain imaging techniques; cognitive function through a series of ‘thinking activities’; cardiovascular well-being by recording blood pressure (BP) and your heart rhythm; fitness levels; dietary intake; and sleep. A blood sample is an optional part of the study and if collected will be used to monitor whether certain bio-chemicals in your body change. A stool sample is another optional part of the study and if collected will be used to monitor whether what makes up the gut changes.

This research will add to our understanding of two of the major causes of death, disability and reduced quality of life in our society: dementia and stroke.

1. **General overview of the research project?**

We will invite people who have had a stroke within the past 2 months, and are at least 18 years of age, to participate in this study. The study will be carried out over three time-points: 2 months post-stroke (this will be considered as ‘Baseline’), 4 months post-stroke (which is 2 months after Baseline), and 1 year post-stroke (which is 10 months after Baseline).

In this study you will be randomly assigned to one of two home-based exercise programmes: either Balance training only or Physical fitness training (these programmes are described in more detail in Section 5 of this document). This is 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 (i.e., random allocation into exercise group). The two exercise groups will be compared to determine whether exercise can lessen the damaging effects that continue after a stroke; specifically, brain volume reduction, cognitive decline, and cardiovascular disease.

Prior to the Baseline assessment, one of the study investigators will visit you at your home to assess the safety of the area where you will be exercising during the intervention. You will be asked to nominate a friend or family member as an emergency contact who will need to be present during this home visit. The study investigator will make a decision about whether this person needs to attend all of the future exercise sessions, or not. You will then be asked to attend Visit 1, which is the initial (Baseline) assessment.

Throughout the 10 month study, the following will be carried out at each Visit time-point unless stated otherwise:

* A demographic and medical history questionnaire.
* Magnetic Resonance Imaging (MRI) scan to measure brain volume.
* Cognitive, mood, and wellbeing assessments using paper-and-pencil and computerised tests.
* A fitness test using a ‘stepper machine’ at different levels of intensity.
* An assessment of sense and motor ability – 2 months and 4 months post-stroke only
* Ambulatory blood pressure and electrocardiogram (ECG) monitor that measures your blood pressure and electrical activity generated by your heart during each heartbeat throughout a 24 hour period.
* An optional blood sample to measure hereditary factors (genes) and other blood markers that may be important in dementia.
* An optional stool sample to assess the composition of the gut.
* Physical activity monitoring to assess your activity during a 7-day period.
* Dietary monitoring to assess your intake over a 3-day period.
* A physical activity questionnaire to assess your typical physical activity levels (also administered via telephone at 6, 8, 10 months after your stroke)
* Sleep monitoring with a 7-day Sleep Diary and one sleep questionnaire.

At the end of the whole study, we will ask you questions about your experience undertaking exercise training at home after your stroke.

**How many people will be taking part in the project?**

Overall, 120 people will be participating in this project.

1. **Where will the tests be performed?**

The MRI brain scan, cognitive assessment, blood draw (if you agree), and fitness tests will take place at [insert name of site]. The location of the study means that doctors are available at all times during the study to provide short-term medical care for any complications or adverse reactions resulting from participation in the study. There is also an option to complete the cognitive assessments remotely using video conferencing technology from within your own home.

The exercise program will be completed in your own home. A trained exercise professional will facilitate all these sessions via Zoom or other videoconferencing technology to oversee the program and your safety. We will deliver all of the equipment you will need for the eight weeks, at no cost to you.

1. **What does participation in this research involve?**

**Consent**

Before participating in the study, we will ask you for your consent.

You may have been introduced to this study whilst still an inpatient at [insert name of site] and provided consent whilst still on the ward. Alternatively, if you wanted more time to consider your involvement in the study, we will phone you soon after your discharge to ask if you have any further questions. If you are then willing to participate, we will ask you to return the completed ‘Consent Form to Participate in the study’ (Page 15 of this document) in the reply-paid envelope provided. Once we have received your signed and completed Consent Form, we will arrange for one of the Investigators to come to your home for a pre-exercise home visit.

If you were first invited to take part in the study over the telephone and received this consent form via mail, please do not sign it and return it to us until after we contact you again to discuss the study further and answer any questions you may have. If, after that time you are willing to participate we will ask you to return the completed ‘Consent Form to Participate in the study’ (Page 15 of this document) in the reply-paid envelope provided. Once we have received your signed and completed Consent Form, we will arrange for one of the Investigators to come to your home for a pre-exercise home visit.

Study Partner

If the study investigator who attends your home safety visit thinks it is necessary that you have a friend or family member in your home during the exercise sessions, we will ask this person to formally become your ‘Study Partner.’ In this case, they will need to sign a separate consent form.

**Timing and procedures/investigations**

**Pre-exercise home visit**: One of our Exercise Professionals and/or Occupational Therapists will visit your home to assess the safety of the area you will be exercising in and minimise potential risks. We require that your emergency contact person attend this visit to meet our staff members and provide their contact details.

**The 3 study visits:**

* Visit 1 (2 months post-stroke, Baseline), completed over two days: Demographic and medical history questionnaire; Blood sample; Kit provided to complete stool sample (to be completed at-home and brought back on day two); MRI scan; Cognitive, Mood, Well-being, and Physical Activity Tests; Fitness test; Fitting of a Blood Pressure and ECG monitor (for 24 hour wear, to be brought back on day two); Fitting of Physical Activity monitor; Delivery of 7-day Sleep Diary and sleep questionnaire for completion during Physical Activity monitor use (to be returned via a reply-paid envelope); Explanation of Dietary Intake app (to be completed over 3 days in the week following Visit 1) – approx. 4 hour visit.

*In-between Visit 1 and Visit 2*: 8 week exercise programme to be undertaken in your home. We will have a friend or family member’s details as an emergency contact, or we may ask that your study partner attends each of the sessions with you.

* Visit 2(4 months post-stroke), completed over two days: Demographic and medical history questionnaire; Blood sample; Kit provided to complete stool sample (to be completed at-home and brought back on day two); MRI scan; Cognitive, Mood, Well-being, and Physical Activity Tests; Fitness test; Collection of the Blood Pressure and ECG monitor (for 24 hour wear, to be brought back on day two); fitting of a Physical Activity monitor; Reminder to complete Dietary Intake app (to be completed over 3 days in the week following Visit 2); and delivery of a 7-day Sleep Diary and sleep questionnaire for completion during Physical Activity monitor use (to be returned via a reply-paid envelope) – approx. 3.5 hour visit.
* Visit 3 (1 year post-stroke), completed over two days: Demographic and medical history questionnaire, Blood sample; Kit provided to complete stool sample (to be completed at-home and brought back on day two); MRI scan; Cognitive, Mood, Well-being, and Physical Activity Tests; Fitness test; Fitting of a monitor that measures ambulatory blood pressure and ECG (for 24 hour wear, (for 24 hour wear, to be brought back on day two)); Reminder to complete Dietary Intake app (to be completed over 3 days in the week following Visit 3); and delivery of a 7-day Sleep Diary and sleep questionnaire for completion during Physical Activity monitor use (to be returned via a reply-paid envelope) – approx. 4 hour visit.

**Final Phone Call**: Interview about the experience of undertaking post-stroke exercise.

**Explanations of procedures/investigations**:

**MRI and Health Questionnaire**

Before you consent, we will conduct a pre-study assessment questionnaire to ensure that you are eligible for the study. After your consent a more thorough MRI assessment questionnaire will be conducted with the study investigator, as well as a questionnaire on your general health and medical history. We will also carry out a review of your medical notes if you have attended clinics at [insert name of site] for your regular care to cross-check the questionnaire against your medical history.

**Blood sample**

A blood sample will be taken by trained staff at each study visit. Where possible, this will be done when you are having routine bloods taken for another reason (e.g., to check your cholesterol or other routine bloods during your appointment to the cardiology clinic) so you will not need to have an extra needle.

In total, 37 mls of blood (which equates to just less than 2 tablespoons) will be drawn at Visit 1. In Visit 2 and Visit 3 the blood sample will be less and 27 mls will be required (1⅓ of a tablespoon). If we cannot obtain the additional 10 mls of blood at Visit 1, we will do this at Visit 2 or Visit 3.

The blood sample will be stored in a locked freezer in the study laboratory only accessible by the study researchers and later analysed for genetic factors and blood markers that may be important in the development of dementia or heart disease. The blood test is an optional part of this study and requires separate consent. You can still participate in this study even if you choose not to consent to a blood sample being taken.

**Stool sample**

At each study visit, you will be provided with a kit to take home in order to complete a stool sample in the days following your visit. Once you have collected the sample, we ask that you store the sample container in your freezer at home until you return it with your 24-hour BP machine on day two of your assessments. You will also be provided with a thermo bag to put the sample in when you bring it back to the facility.

The stool sample will be stored in a locked freezer in the study laboratory only accessible by the study researchers, and later analysed to investigate what components make up the gut. The stool sample is an optional part of the study and requires separate consent. You can still participate in this study even if you choose not to consent to collecting a stool sample.

**The MRI scan**

An MRI brain scan uses changes in magnetic fields to image the brain. No radiation is involved, but the use of magnetic fields means that people with implanted metal (such as pacemakers and certain surgical clips) cannot have an MRI scan for safety reasons. You will be required to complete a questionnaire before your scan to make sure you don’t have any implants that are not suitable for an MRI scan. If, after processing the MRI safety check, the radiographers at [insert name of site] determine that you are unable to have an MRI scan, we will need to withdraw you from the study. If you are able to have an MRI scan, you will be required to lie flat and still in the MRI scanner for approximately 65 minutes.

**Cognitive, Mood, Well-being, and Physical Activity Tests**

You will be asked to complete a cognitive, mood, and physical activity assessment at each time-point (2 months, 4 months, and 12 months, post-stroke). This takes approximately 90 minutes. The cognitive assessment comprises of paper-and-pencil and computerized tasks, which assess memory, attention, language, and processing speed. The mood assessment comprises of paper-and-pencil questionnaires, which assess anxiety, depression, quality of life, and fatigue levels. The physical activity questionnaire asks 10 questions about your usual physical activity levels. All of these cognitive, mood, well-being, and physical activity tasks are widely used in research. You can either complete these tests in-person at our clinics, or via video conferencing technology from within your own home.

**Fitness test**

The fitness test will take about 30-60 minutes to complete, including set-up time. A stepper machine will be used and each 2 minutes the stepper resistance, or difficulty, will get a little bit harder. The intensity of the test will not be at your maximum level, but your breathing and heart-rate will be measured throughout. A trained exercise professional will be present throughout the test to ensure your safety.

The test will serve two purposes:

1. It will help the investigators work out an appropriate exercise programme to match your fitness level; and

2. Measure how fitness levels change as a result of undertaking an exercise programme.

**Exercise programmes** (Between Visit 1 and Visit 2): The exercise programme will occur 3 times per week for a duration of 8 weeks. The programme will take place in your own home, and we will arrange for exercise equipment to be delivered to you. At each of these exercise sessions a trained exercise professional associated with this study will be present via videoconferencing technology.

Details of the Exercise programmes

You will be randomly allocated to one of two structured exercise programmes. The individual activities undertaken in each of the exercise programmes will vary depending on each participant’s fitness level and will be progressed over the 8 weeks to match any changes/improvements you might be making. Each exercise session will involve about 1 hour of activities.

**Ambulatory Blood Pressure and ECG Monitoring**

Ambulatory blood pressure and ECG monitoring is when your blood pressure and electrical activity of your heart during each heartbeat is being measured together at regular intervals as you move around, living your normal daily life. It uses a small lightweight digital monitor that is attached to a belt around your body and connected to a cuff around your upper arm to measure your blood pressure and to electrodes that are placed on your skin around the chest area to detect the heart’s electrical activity. The machine takes your blood pressure by inflating the cuff around your upper arm and then slowly releasing the pressure. The cuff stays on your upper arm for the full 24 hours. It is small enough that you can go about your normal daily life and sleep with it on.

The device will be fitted by the study investigators during the first day of each of your visits and after 24 hours, you will be able to remove the cuff and portable monitor. You will bring the blood pressure monitor back with you to the second day of your Visit.

**Physical Activity Monitor**

At each of your Visits, you will be given a small electronic activity monitor to wear. This monitor is light, unobtrusive, and is worn on like a watch on the left wrist. You will be asked to wear the monitor all day, for a total of 7 days. The monitor is waterproof, so you can wear it while showering or swimming. The monitor will allow us to measure your level of activity during this period. You will be provided with a pre-paid postage envelope to return the monitor at the end of the 7 day period.

In addition to the electric monitoring device, you will be provided with an activity diary to fill in daily.

**Sleep Assessment**

You will be given a 7-day day Sleep Diary and sleep questionnaire to fill in during the same periods of Physical Activity monitor use (as above). The Physical Activity monitor also tracks your sleep activity levels, and the daily Sleep Diary will assess how you rate the quality of your sleep while you wear the monitor. The sleep questionnaire is a 10-question survey of your sleep over the previous month, and is expected to take approximately 10-20 minutes to fill in. Both the Sleep Diary and sleep questionnaire have been widely used in the research community. You will be provided a reply-paid post envelope to return the Sleep Diary and sleep questionnaire with your Physical Activity monitor.

**Dietary Intake Application**

You will be shown how to download a dietary intake app onto your smart phone at Visit 1, and asked to complete a 3-day food diary in the week following each of your study visits. When you have completed the food diary, you will “share” your results via the app with our study nutritionist.

1. **Do I have to take part in this research project?**

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 you take part or not.

## What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any direct benefits from this research study. However, your assistance will provide valuable information in increasing the medical knowledge and understanding of post-stroke management and protection against dementia.

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

*Possible risks, side effects and discomforts from the MRI include:*

* Claustrophobia or anxiety from the small space you will be in for the MRI scan.
* Discomfort from the noise of the MRI scanning (loud banging noise, like a jackhammer).

*Possible risks related to blood taking:* There are a few minor risks related to blood taking. It’s very rare but a person can sometimes feel faint and nausea at the time of blood collection. The blood will be taken from your arm and there is a small risk of bruising at the blood site. Only trained staff will take blood. Sterile and disposable equipment will be used and routine procedures that minimises risk from infections and injury will be followed.

*Possible risks related to exercise:* There are few risks based on the exercise programmes in this study. The questions we ask you during the screening process will help identify your safety to undertake the exercise programmes. Furthermore, before participating you will need to be medically cleared by a consulting physician. All activity programmes and exercise sessions will be devised and delivered in accordance with international sporting guidelines. It is not expected that you will be exercising at an intensity that is likely to induce a major adverse event. Your exercise sessions will be supervised via videoconferencing technology at all times by a trained exercise professional with basic life support skills. In an emergency, we would contact either the friend or family member you nominated as an emergency contact, or emergency service, as appropriate. Any adverse events will be recorded and followed-up.

1. **What will happen if my MRI brain scan shows unanticipated abnormalities?**

You will be provided with the results of your MRI Brain scan. If the MRI Brain scan detects an abnormality that is not already known and requires further investigation, you will be contacted and through your GP be referred to an appropriate member of a clinical team who are not a part of this project.

## What will happen to my blood samples?

If you consent for blood samples to be collected, some of your blood will be used to check for a gene called ‘apolipoprotein E’ or ‘APOE’ for short, and to check for blood proteins of interest. The APOE gene determines the levels of a cholesterol-carrying blood protein which delivers cholesterol to the nerve cells which use it for the repair and establishment of new connections. There are 3 common types of the APOE gene in people: APOE2, APOE3 and APOE4. We all have 2 copies of the APOE gene in our blood, one from our mother and one from our father. Your APOE type is determined by your genetics. The APOE4 type is thought to increase the risk of stroke and dementia.

It is anticipated that future research in dementia will generate further new genetic and blood markers for measurement. At the current point in time, research pathways into such markers and their measurement techniques are not known. If and when the Investigators of this study become involved in such research, an application for approval to use your blood sample will need to be made to the Reviewing Human Research Ethics Committee. The purpose of this application will be to ensuring that no adverse events (i.e., no impact on your health, well-being, quality of life, or socio-economic status) are incurred. In the case that this approval is given, your stored blood sample will enable us to study new and future markers and will be kept until it is all used up. In the case that your blood sample is used, you will remain de-identified. Your blood samples will be used for research purposes only. If at any point you wish to have your samples withdrawn from potential usage then this can be discussed with the Principal Investigator.

1. **Are the blood tests optional for this study?**

Yes. If you do not wish to have your blood tested, you can still be involved in the project. You will be asked to provide a separate consent for the collection of your blood during the research project.

1. **Will I be told the results of the blood analyses?**

You can choose whether or not you would like to be informed of your APOE4 gene status by ticking the appropriate box on the ‘Consent Form to Participate in genetic and blood factors analyses’, (page 15 of this document). If you decide to receive the result of your APOE4 gene status, you will be contacted by a member of the research team once the blood sample has been analysed.

The results relating to the remaining genetic and blood markers will only relate to markers of dementia and heart disease. It will not generate information that you will be legally required to disclose to a third party (such as employment agency or insurance agency), or that will be of any social significance. Nor will the information be used for any purposes other than research. As the significance of these genetic and blood markers is not yet known, ***the information obtained in this research will not be disclosed to you following the study*** as they are not performed in standard clinical care.

**12.a. What does this mean for me and my family?**

Having 2 copies of APOE4 puts you at higher risk of stroke and dementia. This means it will be very important for you and your doctors to keep all your risk factors (blood sugar, blood pressure, cholesterol) under control. It has no specific implications for your family, but if your family is concerned we can arrange genetic counseling. At present, APOE4 testing is not done under Medicare, and can only be done outside research studies at the patient’s cost.

**12.b. Will this have implications for my insurance?**

Insurance companies sometimes ask about genetic conditions. This may have implications for life insurance for you. As everybody has some type of APOE, this will not have implications for insurance for any of your family members.

**12.c. Will the people testing my blood be able to identify me?**

No one apart from the study researchers will have access to these samples and your personal information will not be attached to the results. A unique identification number will be allocated to each participant involved in the study. The stored blood samples and the study database will only contain this unique identifier and be kept separately from your hospital number and personal information.

**12.d. Where will the blood be tested and stored?**

Blood samples will be stored temporarily in freezers in locked rooms [for Austin, Eastern and Epworth Health: within the Florey Institute of Neuroscience and Mental Health; for Western Health: in the Western Centre for Health Research and Education] before being transported for permanent storage in locked freezers in locked rooms within The Alfred Centre, Monash University.

## Are the stool samples optional for this project?

Yes. If you do not wish to provide a stool sample, you can still be involved in the project. You will be asked to provide a separate consent for the stool collection during the research project.

## What will happen to my stool samples?

If you consent for stool samples to be collected, some of the samples will be examined to find out what type of genetic material is living in your gut (for example, bacteria). Research pathways into gut composition and how it affects our health are in their early stages. It is anticipated that future research will generate further new markers for measurement. If and when the Investigators of this study become involved in appropriate research, an application for approval to use your stool sample will need to be made to the Reviewing Human Research Ethics Committee. The purpose of this application will be to ensure that no adverse events (i.e., no impact on your health, well-being, quality of life, or socio-economic status) are incurred. In the case that this approval is given, your stored stool sample will enable us to continue to investigate gut composition, and will be kept until it is all used up. In the case that your stool sample is used, you will remain de-identified. Your stool samples will be used for research purposes only. If at any point you wish to have your samples withdrawn from potential usage then this can be discussed with the Principal Investigator.

## What if new information arises during this research project?

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you.

## Can I have other treatments during this research project?

Your participation in this project does not affect any of your other treatments.

## What if I withdraw from this research project?

You are free to withdraw from this project at any time. If you decide to withdraw, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

If you decide to leave the project, the researchers would like to keep any of the data that may have already 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.

## How will I be informed of the results of this research project?

Once the project is completed and final results known, you will be sent a written summary. This will list the findings and if and where the results have been published or presented.

If, at the completion of the study (after Visit 3), you wish to receive feedback regarding your individual progress for the Fitness and Cognitive testing aspects of the study, we will provide you with a brief letter indicating how you performed in relation to other people your age. We will also provide some general recommendations for how you can follow-up with your brain and body health, should you have any concerns about these aspects.

Part 2 – How is the research project being conducted?

## What will happen to information about me?

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to discuss the findings with other members of Monash University. Results may be presented at neurological conferences and published in medical journals. There will be no commercial development of the research results.

Collaborating research teams may request in writing to use data collected as part of this project for extended (related research) or unspecified (any future research). Any data shared in this capacity or in any publications and/or presentations will be provided in such a way that you cannot be identified, except with your permission. Data obtained through the MRI scan has no identifying features attached (name, date of birth, etc). You will be assigned a unique and coded number for the study, and any reference to your specific details will be made via this number. Data will be stored in an unmarked locked filing cabinet in a locked office in [insert name of site]. The data will be kept for a period of 7 years, after which time paper records will be shredded and electronic records wiped and discarded.

Information about you may be obtained from your health records held at this, and other, health services for the purposes of this research. It is desirable that your local doctor be advised of your decision to participate in this research project. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research project. Information about your participation in this research project may be recorded in your health records.

1. **What happens if I am injured as a result of participating in this research project?**

If you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

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

1. **Reimbursement**

You do not have to pay to participate in this study, for the exercise program, or for the hire of the exercise equipment. You will not be paid for your participation in this research. A parking space will be available for you at [insert name of site], for each visit. This means you will not need to look, or pay, for parking. Any parking costs associated with attending the assessments will also be paid by the study. All postage costs will be pre-paid by the study.

1. **Who is organising and funding the research?**

This research project is being conducted by Monash University. It is funded through research grants provided by the National Heart Foundation and National Health Medical Research Council (NHMRC).

1. **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 Austin Health HREC.

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.

## 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 Researchers:

Professor Amy Brodtmann Dr Philip Choi (Eastern Health)

Role: Principal Investigator Role: Principal Investigator

Telephone: 9035 7004 Telephone: 9895 3352  
  
Professor Tissa Wijeratne (Western Health) Prof Gavin Williams (Epworth Health)  
Role: Principal Investigator Role: Principal Investigator

Telephone: 0430 048 730 Telephone: 9426 6094

or either of the following people:

Name: Dr Jean Sebastien Teoh Name: Ms Kim Adkins

Role: Associate Investigator Role: Associate Investigator

Telephone: 0411 201 726 Telephone: 0419148085

Name: Ms Ruwayda Haibe Name: Ms Elizabeth McInerney

Role: Associate Investigator Role: Associate investigator

Email: Ruwayda.haibe@monash.edu Email: Elizabeth.McInerney@monash.edu

**Complaints contact person**

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

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

1. **For more information about ethical issues/ complaints**

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 the reviewing Austin Health HREC Executive Officer:

|  |  |
| --- | --- |
| **Name** | Manager – Office for Research |
| **Telephone** | 03 9496 5088 |
| **Email** | [ethics@austin.org.au](mailto:ethics@austin.org.au) |

**Human Research Ethics Committee**

**LIST OF QUESTIONS FOR POTENTIAL PARTICIPANTS**

**TO ASK INVESTIGATORS ABOUT RESEARCH INVOLVING GENETIC TESTING**

# You have been invited to participate in research involving genetic materials.

You may be interested in asking the researcher these questions after you have looked over the written information, and before you consent to be involved in the research project.

1. What do you think you might find out in this research?
2. Will I be able to get my results?
3. Who else will get a copy of my results?
4. If I choose to find out the results, what will this mean to me?
5. If I agree to participate what arrangements have been made for my independent counselling and who is the independent counsellor?
6. How might the results affect my family?
7. If I choose to get the results, how long will it be before I get them?
8. If I choose to get the results, who will help me to understand what they mean for me and my family?
9. What will happen to my **specimen or sample**? Will it be used in other studies?
10. Will my results have any effect upon my job, my being able to get insurance, **or my status in legal matters**?

# What will happen if this research leads to the manufacture of commercial products?

**For more information about ethical issues/ complaints concerning this research you may contact:**

|  |  |
| --- | --- |
| Name | Dr Sianna Panagiotopoulos |
| Position | Reviewing HREC Executive Officer |
| Telephone | 03 9496 4090 |
| Email | [ethics@austin.org.au](mailto:ethics@austin.org.au) |

There is more general information about research ethics issues at <http://www.nhmrc.gov.au/your_health/egenetics/index.htm>

**Consent Form to Participate in the study**

**Title** Post Ischaemic Stroke Cardiovascular Exercise Study –

Zoom Delivered Intervention Against Cognitive Decline (PISCES-ZODIAC)

**Protocol Number:** HREC/16/Austin/45

**Project Sponsor:** Heart Foundation and National Health Medical Research Council

**Principal Investigators:** Professor Amy Brodtmann, Dr Philip Choi, Professor Tissa Wijeratne, Professor Gavin Williams

**Associate Investigators:**  Dr Jean Sebastien Teoh, Ms. Kim Adkins, Ms Ruwayda Haibe, Ms Elizabeth McInerney

**Location** [Insert name of site]

## Declaration by Participant

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it*.*

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash University concerning my disease and treatment that is needed for 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.

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

Name of Participant (please print)

Signature

Date

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

Witness to the informed consent processName (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 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 Senior Researcher

(please print)

Signature Date

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

**Consent Form to Participate in genetic and blood factors analyses**

**Title** Post Ischaemic Stroke Cardiovascular Exercise Study –

Zoom Delivered Intervention Against Cognitive Decline (PISCES-ZODIAC)

**Protocol Number:** HREC/16/Austin/45

**Project Sponsor:** Heart Foundation and National Health Medical Research Council

**Principal Investigators:** Professor Amy Brodtmann, Dr Philip Choi, Professor Tissa Wijeratne, Professor Gavin Williams

**Associate Investigators:**  Dr Jean Sebastien Teoh, Ms Kim Adkins, Ms Ruwayda Haibe, Ms Elizabeth McInerney

**Location** [Insert name of site]

**Blood sample**

I consent to the blood test for APOE and quantification of proteins of interest.

I understand that these blood tests are optional.

APOE: □ Yes □ No

Other proteins of interest: □ Yes □ No

I wish to receive a APOE genetic test result: □ Yes □ No

I consent to the storage and use of this blood sample in:

* this specific research project
* other research that is closely related to this research project
* any future research

as described in Section 10 of this document by the study investigators.

Name of Participant (please print)

Signature

Date

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

Witness to the informed consent processName (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 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 Senior Researcher

(please print)

Signature Date

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

**Consent Form to Participate in stool sample analyses**

**Title** Post Ischaemic Stroke Cardiovascular Exercise Study –

Zoom Delivered Intervention Against Cognitive Decline (PISCES-ZODIAC)

**Protocol Number:** HREC/16/Austin/45

**Project Sponsor:** Heart Foundation and National Health Medical Research Council

**Principal Investigators:** Professor Amy Brodtmann, Dr Philip Choi, Professor Tissa Wijeratne, Professor Gavin Williams

**Associate Investigators:**  Dr Jean Sebastien, Ms Kim Adkins, Ms Ruwayda Haibe, Ms Elizabeth McInerney

**Location** [Insert name of site]

**Stool sample**

I consent to providing a stool sample for analysis of the composition of the gut.

I understand that providing a stool sample is an optional part of the study.

□ Yes □ No

I consent to the storage and use of this stool sample in:

* this specific research project
* other research that is closely related to this research project
* any future research

as described in Section 14 of this document by the study investigators.

Name of Participant (please print)

Signature

Date

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

Witness to the informed consent processName (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 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 Senior Researcher

(please print)

Signature Date

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