PARTICIPANT INFORMATION STATEMENT

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**Assessment of neurovascular function and cognition in adult patients with complex congenital heart disease**

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| **INVESTIGATORS** | **ROLE** |
| Dr Nicholas Collins | Principal investigator |
| Dr Rachel Wong | Co-investigator & Study Coordinator |
| Prof Chris Levi | Co-investigator |
| Prof Neil Spratt | Co-investigator |
| Prof Peter Howe | Co-investigator |
| Prof Andrew Boyle | Co-investigator |

You are invited to participate in the research project identified above which is being conducted at The University of Newcastle by Dr Rachel Wong and Professor Peter Howe of the Clinical Nutrition Research Centre, Professor Andrew Boyle of the University of Newcastle and Dr Nicholas Collins, Professor Chris Levi and Professor Neil Spratt of the John Hunter Hospital.

why is the research being done?

Adults with congenital heart disease have excellent survival rate. However, late complications such as early-onset of cardiovascular events can affect quality of life later in life. We have recently demonstrated that adults with previous aortic coarctation repair (a procedure to correct narrowing of the heart’s main artery) have increased stiffening of the blood vessel in the brain, which may explain the heightened risk for stroke in this group of patients. The hardening of the blood vessel in the brain decreases the ability of the vessels to dilate effectively, thus decreasing blood flow in the brain. Over time, this can lead to poor mental performance and increases one’s risk for early-onset dementia.

In this study, we are looking to examine whether patients with complex congenital heart disease may have disturbances in the blood flow in their brain and how this affects mental performance. We will use transcranial Doppler ultrasound (TCD) to measure blood flow in the brain during a series of mental tests and compare patients with complex congenital heart disease with healthy control participants.

who can participate in this study?

We are seeking a total of 30 participants - 15 adults with complex congenital heart disease and 15 adults without heart disease. Participants will be recruited via public advertisement, word of mouth and referral from the cardiologists at the John Hunter Hospital.

**This study is suitable for you if you:**

* Understand the procedures involved and agree to participate in the study by giving written informed consent.
* Aged between 18 and 85 years.
* Have a measurable ultrasound signal in both left and right sides of your head (we will assess this during screening visit 1).
* Have complex congenital heart disease to be considered into the patient group or have no heart disease to be considered for the control group.

**This study is NOT suitable for you if you:**

* History of cerebrovascular events including transient ischemic attack.
* Have uncontrolled hypertension (>160/100mmHg) (determined at the visit to clinic at the University’s Callaghan campus).
* Have other medical conditions or are taking medications that (in the opinion of the chief investigator) may interfere with the study outcomes.

What is involved?

Study site: University of Newcastle, Callaghan, Medical Sciences Building, Level 3 Room MS304.

No. of visits: 1

Duration: up to 2.5 hours

What to expect at your visit?

Upon arrival, the project will be explained to you by the study coordinator. Here, you will have the opportunity to ask questions before signing the consent form, which allows us to proceed with the following assessments:

* Height, weight and waist circumference
* Blood pressure measure to determine whether you meet the study’s blood pressure criteria.
	+ After sitting down quietly for 10 mins, a blood pressure cuff will be placed on your upper arm. The blood pressure machine, similar to the ones used at your GP, will inflate and your blood pressure will be determined automatically.
* Detecting blood flow signal using ultrasound.
	+ If your blood pressure is less than 160/100mmHg, you will be fitted with a head piece with ultrasound probes on either side of your forehead. This device monitors blood flow in your brain and is the main assessment tool of the study.



Please note: Due to individual differences in bone density and changes in bone density with age, we may not obtain a measurable signal. This is a limitation of the ultrasound technique. However, this blood flow signal measurement is important for the success of the study. Therefore, only volunteers in whom this test can be performed will be included in the study.



* Thinking tests
	+ You will be asked to do a series of thinking tests on the iPad and on paper. Some tests will be easy and some will be challenging.
	+ The ultrasound will continuously record the changes in blood flow in the brain while you do these thinking tests.
	+ At the end of the thinking test, you will be asked to open and close your eyes as guided. During the ‘eyes open’ condition, you will be presented with a checkerboard pattern on a monitor (participation is optional).
* Walk test
	+ As a secondary objective, we want to see whether walking speed is related to mental performance and blood vessel function in the brain.
	+ You will be asked to walk at your normal walking speed in an open hallway, marked at a distance of 4 metres and 20 metres. A practice trial preceds the timed trials.

Reimbursement

Participants who complete the study will be offered $30 in compensation for their travel and parking expenses. Participants who are excluded from the study at the screening visit will receive $10. There will be no reimbursement for participants who do not attend.

what choices do you have?

Participation in this study is voluntary. Only participants who give their informed consent will be included in the study. A decision not to participate will not disadvantage you.

If you decide to participate, you may withdraw from the study at any time without prejudice and without giving a reason. If you choose to withdraw from the study, you can choose to withdraw any data collected from you up until the time the data is included in the study analysis.

The study investigators may also stop your participation in the study, with or without your consent, if they feel that it is in your best interest.

The study may also be stopped by the Ethics Committee to protect the rights and welfare of the study volunteers.

what are the risks and benefits of participating?

All procedures will be carried out by qualified personnel and in accordance with Work Health & Safety guidelines. However, to help you make an informed decision, the risks and benefits associated with the various procedures are set out as follows:

**Risks:**

Monitoring blood flow in the brain

Ultrasound is used to measure blood flow in the brain. This is comparable to the ultrasound test that is routinely performed on pregnant mothers and is harmless. The device sits snugly around your head just above your eyebrows. If the headpiece becomes uncomfortable, please notify the investigator who will re-adjust the device to suit.

Light stimulation

There may be a chance of tired eyes from exposure to the light from a computer monitor. To minimise risk, you will keep your eyes on the screen for no more than 1 minute.

Thinking tests

Some participants may feel mildly distressed when completing the thinking tests, as many of the tasks require you to respond quickly or complete a number of tasks simultaneously. However, all volunteers should feel assured that high performance levels on the tests are not expected. You may be distressed if you think you are not performing well on these tests but this could be for a number of reasons and we will talk to you about your results and you can also talk to your usual GP about them.

If you have previous or on-going concerns with your memory or mental performance, you may wish to seek advice from your GP before your screening visit.

Walking test

There is a slight risk of losing your balance, rolling of the ankles or slipping in the walking test. Proper footwear (i.e. flat shoes or athletic shoes) must be worn for the locomotive test. The investigator will also walk alongside you if you feel unsteady on your feet. The open hallway is brightly lit, dry and free from obstacles before test commencement. Participation in this walking test is optional.

**Benefits:**

You may not benefit from being on this study.

At the conclusion of the study, participants will be given a summary of findings of the group results in the form of a newsletter. No individual results will be released to participants.

How will your privacy be protected?

Any information collected by the investigators which might identify you will be stored securely and only assessed by the investigators unless you consent otherwise, except as required by law.

A numeric identification code will be assigned to volunteers who express interest in the study. This numeric identification code will be used in all hard copies and electronic records of the data collected from each volunteer. Only the investigators of this study will have access to these records for the duration of this intervention. However, sharing of de-identified participant data with other investigators may be possible for future ethically approved research.

The Health, Diet & Lifestyle questionnaire which you will return by post, or via email, will bear the numeric identification code and responses entered into a spreadsheet that is protected by a password. If this study is not suitable for you, your Health, Diet & Lifestyle Questionnaire will be destroyed immediately.

During statistical data analysis, the database will be stored in a password protected computer file on a computer that is kept in a locked room.

All data for the study will be retained on file and on site by the principal investigators at Hunter New England Health, in a locked data storage site for a period of five years and destroyed and electronic files deleted thereafter. Electronic files are secured by password only known to the investigators of this study.

How will the information collected by used?

Data collected in this study will be submitted for publication in scientific journals and presented at conferences. All individual data sets will be retained by the study investigators.

Individual volunteers will not be identified in any reports arising from the study.

At the conclusion of the study, participants will be given an overall group summary of findings.

What do you need to do to participate?

Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact the investigators at the University of Newcastle, Dr Rachel Wong (4921 6408) during working hours or email: rachel.wong@newcastle.edu.au.

If you would like to participate, please complete, sign and return the Health, Diet & Lifestyle Questionnaire. The purpose of the Questionnaire is to collect information about your lifestyle, medical history and details of any medications you are taking. It is important that you provide the study staff with as much information as possible about your medical history and current health and medication use, as these may affect whether or not you are able to participate in the study.

In the questionnaire, you will have the option whether or not you would like to be contacted for future studies. However, you are not obligated to participate in future studies and you may withdraw your consent to be contacted anytime without prejudice. Please contact Dr Wong if you did not receive the questionnaire.

Upon receipt of signed Health, Diet & Lifestyle questionnaire, we will determine whether this study is suitable for you before inviting you to come in for the screening/baseline visit.

At the screening visit, the study coordinator will explain the study and answer your questions pertaining to the study. If you decide to participate in the study, you will then sign a Consent Form before proceeding with the screening assessments.

further information

Parking

Limited visitor parking spots (free) are available. The investigators are unable to reserve a spot for you as they are available on a first come first served basis. A Visitor Parking Permit will either be mailed to you following confirmation of your clinic appointment or you can obtain the Permit on site from the Study Coordinator. In the event that free parking is not available the Study Coordinator may be able to make other arrangements. Paid parking is also available at the Callaghan Campus in areas marked ‘General Parking’ for $4.40 per day. Participants will be offered compensation for their travel and parking expenses.

For more information, please contact Dr Rachel Wong (4921 6408; rachel.wong@newcastle.edu.au), Thank you for considering this invitation to participate in research undertaken at the University of Newcastle.

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| Dr Nick Collins Principal investigator,John Hunter Hospital | Dr Rachel WongStudy coordinator, Co-investigator 1University of Newcastle  | Professor Peter Howe Co-investigator 2University of Newcastle |
| Professor Chris Levi Co-investigator 3John Hunter Hospital  | Professor Neil Spratt Co-investigator 4John Hunter Hospital  | Professor Andrew BoyleCo-investigator 5University of Newcastle |

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, Reference: 17/04/12/4.01.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email hnehrec@hnehealth.nsw.gov.au. Please quote the reference number 17/04/12/4.01