Participant Information form

***Project title***

*Physical activity for Better Health and Drive (PhAB-HeaD)*

#### **Researchers**

|  |  |
| --- | --- |
| Professor Nicolas Cherbuin  Australian National University  (02) 2 6125 1558  [Nicolas.Cherbuin@anu.edu.au](mailto:Nicolas.cherbuin@anu.edu.au) | Professor Ben Rattray  University of Canberra  (02) 6201 5145  [Ben.Rattray@canberra.edu.au](mailto:Ben.Rattray@canberra.edu.au) |
| Dr. Joe Northey  University of Canberra  (02) 6201 2263  [Joe.Northey@canberra.edu.au](mailto:Joe.Northey@canberra.edu.au) | **Vicki McCarthy**  PhD Candidate – University of Canberra  [Vicki.Mccarthy@canberra.edu.au](mailto:Vicki.Mccarthy@canberra.edu.au) |

The research team includes

|  |  |  |  |
| --- | --- | --- | --- |
| A/Prof Anne Bruestle | ANU | Dr Jeroen Van Boxtel | UC |
| Dr Richard Burns | ANU | **A/Prof Kate Pumpa** | UC |
| Dr Erin Walsh | ANU | **Dr Amit Lampit** | University of Melbourne |
| Dr Jo Lane | ANU | **Amanda Scott** | UC – MSc candidate |
| Tergel Namsrai | ANU – PhD candidate |  |  |

This project Is funded by the Driving Research Endowment Fund

You are invited to take part in a study on the effect of concurrent physical and cognitive training. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends.

If you agree to take part in this study, you will be asked to sign the Informed Consent Form. Please make sure you have read and understood all the pages of this document.

#### **Project Aim**

The aim of this research is to investigate the relative benefits of cognitive and physical training by themselves or in combination.

#### **Benefits of the Project**

This research project will explore the potential benefit of concurrent physical and cognitive training as a protective mechanism against known cognitive changes due to ageing. This project will serve as the first of its kind to drive clinical guidelines for addressing age related cognitive decline.

#### **General Outline of the Project**

The project will compare three different 12-week training interventions. Participants will be randomly allocated to one of the interventions being either: physical only training involving 50 minutes of moderate-intensity cycling twice per week; cognitive only training involving 50 minutes of training on thinking tasks such as remembering, matching, fast response while being seated in a relaxed environment; or concurrent physical and cognitive training involving 50 minutes of cognitive training whilst cycling at a moderate intensity. Assessments will be conducted before, in the middle and after the intervention and involve cardiovascular fitness, a cognitive test battery, and a dual-task assessment in which participants undergo a physical task with various cognitive tests.

**Inclusion criteria:** Participants are eligible to participate if they are generally healthy, sedentary to recreationally active males or females aged 60 to 75 years living in the community. All participants must be capable of undertaking all aspects of the study and complete a pre-exercise screening.

**Exclusion criteria: I**ndividuals will not be able to participate if they do not successfully complete the pre-exercise screening or have another medical condition or injury that prohibits them from completing the physical activity components of this study. Any known vision or hearing impairments that may prevent the participant from listening to or following instructions will also prevent individuals from partaking.

#### **Participant Involvement**

Participants who agree to participate in the research will be asked to:

1. Complete the following online form to ensure the ability to participate in the study.
2. Receive a phone call from our research team to discuss any questions participants may have, as well as answer a short cognitive function questionnaire verbally (approx. 20 mins)
3. Complete a 2-part at home questionnaire (approx. 30 mins each) Including demographic Information, mental health questionnaires and self-reported physical activity. Participants will also be asked to wear a physical activity monitor for two weeks and complete a dietary questionnaire. The first part to be completed at anytime, the second part to be completed within 2 days of the first visit to the University of Canberra.
4. Perform assessments prior to commencing the Intervention at the University of Canberra across two separate visits/days (three for participants who also participate in a cardiovascular sub-study.

Lab visit 1 will take approximately 1.5-2 hours.   
Lab visit 2 will take approximately 2 hours.

Lab visit 3 (Only for a subset of invited participants) will take approximately (90min).

1. Undergo a 12-week training Intervention that will be randomly allocated. The training Interventions can be summarised as:  
    a. Physical training only - 50 minutes moderate-intensity cycling, twice per week (approx. 20 hours of training).  
    b. Cognitive training only - 50 minutes of cognitive activity whilst at rest, twice per week (approx. 20 hours of training).  
    c. Concurrent physical and cognitive training - 50 minutes of cognitive activity whilst completing moderate Intensity cycling, twice per week (approx. 20 hours of training).
2. Following the 12-week Intervention, complete the follow-up at home questionnaires and Initial assessments at the University of Canberra, Identical to the baseline assessments

**Tasks to be completed by participants**

* A blood sample of 28-30 mls will be taken by a qualified phlabotomist.
* Aerobic fitness will be measured on a stationary bicycle. An incremental test will be carried out whereby you will begin cycling at an easy level and additional resistance will be applied each minute. You will wear a heartrate monitor via chest strap to monitor heart rate throughout the test.
* Arterial stiffness will be measured using a non-invasive sphygmocor machine. The sphygmocor is a non-invasive assessment of the cardiovascular system function, focused on central blood pressures, measures of arterial stiffness and autonomic function; this will take approximately 10 minutes.
* Cerebrovascular health will be measured using non-invasive ultrasound. This equipment allows researchers to record the blood flow within the brain. During this assessment participants will lay on a bed for approximately 15 minutes for resting measures. Following this, you will be seated on a chair and breathe in a gas mixture that is enriched with oxygen and carbon dioxide to see how the blood flow in your brain responds. Finally, we will see how blood flow responds to changes in your posture by alternating between standing and seated measures. During these assessments you will also be fitted with a face mask to measure your expired gas and a blood pressure monitor placed on your finger.
* Participants will complete a short series of computerised tasks. During these tasks, you will sit at a computer screen with one of our researchers and work through these tasks. Before each task you will be familiarised and have plenty of time to practice.
* Participants will be asked to complete at home a survey (approx. 40 minutes) including demographic, health, mental health, physical activity and sleep information. An additional diet survey will be provided for completion prior to beginning the 12-week intervention.
* Participant’s blood pressure will be taken which involves placing a cuff around your upper arm and pumping up the cuff to occlude the artery, this is then released slowly and a measure is taken by listening to the blood come back through the artery. Your heart rate will be monitored by a heart rate monitor by placing a strap below your chest and a wristwatch on.
* Participants will be provided with a small, wrist worn device (actigraph) to record sleep habits and physical activity behvaiour over 14 days. Participants will be required to wear the device for 7 days prior to beginning the 12 weeks of training and for 7 days during the 12 weeks of training for 14 total days.
* Driving skills will be measured using a driving simulator. During this task, participants will sit in a cockpit similar to the interior of a car with a steering wheel, pedals and indicators and be asked to drive through a series of tasks involving adhering to road rules with other traffic.

Participation in the research is completely voluntary and participants may, without any penalty, decline to take part or withdraw at any time without providing an explanation or refuse to answer a question.

**Screening Process**

Prior to participating in the study, you will be asked a series of questions to determine if you are eligible. It will include some medical history information such as cardiovascular disease and mental health information. As the study is aimed at healthy ageing, you will also be required to complete a dementia screening tool to screen for significant cognitive impairment prior to commencement.

***Blood Draw***

The project does not currently have funding to assess blood biomarkers or genetic factors. Blood will be drawn and stored securely at -80C in the event funding is obtained for the future analysis of blood biomarkers and genetic information. Blood samples will be stored for a minimum of 5 years. You will be asked if you consent to the storage and use of your deidentified data and blood sample.

#### **Confidentiality**

Only the researcher/s will have access to the individual information provided by participants. Privacy and confidentiality will be assured at all times. The research outcomes may be presented at conferences and written up for publication. However, in all these publications, the privacy and confidentiality of individuals will be protected.

#### **Anonymity**

All reports and publications of the research will contain no information that can identify any individual and all information will be kept in the strictest confidence.

***Study Withdrawal***

Participation in this study is completely voluntary. Participants may, without any penalty, decline to take part or withdraw from the study at any time without providing an explanation or refuse to answer a question. On withdrawal from the study, and participant request, all data and stored samples (including bloods) will be destroyed, and not be used by any member of the research team in any future publications.

***Future Use of Data***

Participants will be offered to consent only their deidentified study information to a database for potential future use. This will house no personal or identifiable information but may be used to pool the findings from multiple studies to contribute to future findings. Consenting to future use is completely voluntary.

#### **Data Storage**

The information collected will be stored securely on a password protected computer throughout the project and then stored at the University of Canberra for the required fifteen-year period after which it will be destroyed according to university protocols.

***Participant Reports***

A report of participants results from included outcome measures and will be generated giving participants an opportunity to learn about their own cognitive health, cardiorespiratory fitness and driving ability. This will be provided following completion of the intervention and upon individual request.

#### **Ethics Committee Clearance**

The project has been approved by the Human Research Ethics Committee of the University of Canberra (HREC – 11846).

#### **Queries and Concerns**

Queries or concerns regarding the research can be directed to the researcher and/or supervisor.

Contact details are at the top of this form.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the University of Canberra’s Research Ethics & Integrity Unit team via telephone 02 6206 3916 or email [humanethicscommittee@canberra.edu.au](mailto:humanethicscommittee@canberra.edu.au) or [researchethicsandintegrity@canberra.edu.au](mailto:researchethicsandintegrity@canberra.edu.au)

If you would like some guidance on the questions you could ask about your participation please refer to the Participants’ Guide located at <http://www.canberra.edu.au/ucresearch/attachments/pdf/a-m/Agreeing-to-participate-in-research.pdf>