Participant Information Form

Project Title

Physical Activity for Better Health and Drive (PhAB-HeaD)

Researchers

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The research team can be contacted via **PhABHeaD@canberra.edu.au.**
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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 how the results will be used 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: Individuals 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 any time, 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. An additional optional visit (lab visit 3) will only be necessary for a subset of invited participants and will take approximately 1.5 hours.

5. 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).

6. 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 (28-30 mLs) will be taken by a member of the research team trained in venepuncture.
- 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 device called a SphygmoCor to attain a non-invasive assessment of vascular function in large vessels, focused on central and peripheral blood pressures; this will take approximately 10-20 minutes.
- 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 4 of 5 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 temporarily restrict blood flow within the artery, this is then released slowly, and a measure is taken by listening to the blood flow as it returns through the artery.
- Participants will be provided with a small, wrist worn device (actigraph) to record sleep habits and physical activity behaviour 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.

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. The results of genetic testing will not be disclosed to participants and will be deidentified to maintain anonymity of the sample collected.

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 upon individual request on completion of the intervention.

Risks of Participation

All research carries risk. The risks identified from participating in this project, and strategies in place by the research team to mitigate these risks, are outlined below:

COVID-19/General infection: There is a risk of community acquired infections (including the common cold, flu, and COVID-19) through contact with other participants, researchers, and surface transmission (doorknobs, shared equipment). Standard operating procedures relating to regular cleaning practices, appropriate hand and respiratory hygiene, as well as additional surface cleaning throughout the day, will be adhered to by all members of the research team.

Blood draw: Venepuncture at any site carries a risk of subsequent infection, localised pain or bruising. There is an additional risk for lightheadedness, fainting, and blood pressure dysregulation as common side effects of blood exposure or needle insertion. The procedure will be carried out by a trained and experienced member of the research team with venepuncture or phlebotomy certification and using aseptic techniques. Participants will be monitored for signs and symptoms of lightheadedness and other adverse outcomes during and after the procedure by the research team present.

Driving simulation: There may be a risk of nausea or dizziness during the driving simulator task. If a participant has experienced vertigo or motion sickness in their life, we ask that they advise the researcher at the time so that any adjustments may be made, if necessary, to this particular task within the assessment protocol.

Psychological distress: While the components of the study itself pose little risk to participants, there is a chance that completing questionnaires related to psychological wellbeing (e.g., anxiety and depression) and testing for cognitive function and cognitive decline may result in uncomfortable feelings e.g., feeling distressed or sad. If a participant does feel this way, they are Invited to discuss this with the study researchers or contact a support person or support services on the Participant Information Sheet. Research team members interacting with study participants have Mental Health First Aid training and will discuss any concerns they have regarding participants' wellbeing with Dr Jo Lane, a clinical psychologist. If required, Dr Lane will monitor and assess the psychological distress of participants and refer participants to appropriate support services and will debrief members of the research team as required.

Cardiovascular and physical strain: Physical activity carries an inherent risk of cardiovascular events (e.g., heart attack), although this risk is considered very minor. This risk is mitigated through screening participants using the Exercise and Sport Science Pre-Exercise screening tool. This tool is designed to identify those that are at an increased risk of adverse events arising from physical activity engagement. Physical training is also monitored through heart rate responses, further mitigating any risk, and reducing risk of cardiovascular events through the promotion of better health through intervention. All training and assessments sessions involving physical activity will be monitored by a first aid trained researcher. Fatigue is a risk associated with acute exercise. Whilst levels of fatigue are likely to occur, fatigue should be transient and limited, and the design of the intervention has been considered with this in mind. Further, the interventions should reduce fatigue in the long-term, providing a benefit to participants. Short-term, participants will be regularly monitored and self-report fatigue scores. Should fatigue be an on-going issue for a participant, members of the research team will consider options to potentially alleviate issues (e.g., by reducing load, increasing time between training sessions where possible).

Time considerations: Time issues may be a risk for participants given the regular and ongoing commitment of participation in this study. Whilst the research team will seek to limit the number of missed sessions, this is possible and will be accounted for statistically in the final analysis. Further, the research team will provide several training windows during the week to provide a flexible approach to meet study intervention training requirements.

Genetic information: Participants' genetic information will not be disclosed in any instance to mitigate the risk of incidental identification of genetic health risks. All participant samples for genetic sampling will be de-identified and stored in a de-identified format consistent with all measures in this study.

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.

Confidentiality

Only the researchers 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.

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.

Future Research
If you agree, the information collected during the conduct of this research may be used in future research projects on related research areas. Any future use of your data will comply with any conditions imposed by the Human Research Ethics Committee of the University of Canberra.

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.

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 or 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 https://www.canberra.edu.au/research/graduate-research/current-research-students/study/research-project-management/integrity-and-ethics/ethics/accordion/human-ethics/human-ethics-documents/Agreeing-to-participate-in-research.pdf