

PARTICIPANT INFORMATION SHEET

You are invited to participate in a clinical trial to investigate whether dietary changes can delay or prevent the progression of memory loss in older people at risk for dementia

Study Title: Food for thought: Preventing decline and improving cognition through diet and dietary advice in older people at risk

This is a multi-centre study being conducted by the School of Medicine and the School of Psychology at the University of Wollongong (UOW), the School Psychiatry at the University of New South Wales (UNSW) and the Neuroscience Research Australia (NeuRA) Institute, in collaboration with the Illawarra Shoalhaven Local Health District (ISLHD) and the South Eastern Sydney Local Health District (SESLHD). This research also forms a component of the thesis for a PhD student completing a Doctor of Philosophy, and an honours student completing Bachelor of Nutrition and Dietetics (Honours). This research is funded by the Dementia Centre for Research Collaboration under the World Class Research Project Grant funding scheme.

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What is this research about?

Anthocyanins are compounds found naturally in fruits and vegetables that provide the deep-red and purple-blue colour. They have strong antioxidant abilities which may protect the cells of the body from damage.

Previous research suggests that eating foods and beverages that are rich in anthocyanins may help decrease the risk of age-related diseases, such as cancer, heart disease and nervous system decline. Previous trials conducted by our team have found that eating anthocyanin-rich fruit can improve both short- and long-term memory, and verbal fluency in older adults with mild to moderate Alzheimer's dementia (AD) and mixed dementia.

The purpose of this study is to identify if a high intake of anthocyanins through either diet/dietary advice or supplementation for 6 months can sustainably delay or prevent memory loss progression in people at high risk for dementia.

This study will allow scientists to have a better understanding of how anthocyanins work in the body. It will identify if intake will have a significant effect on cognitive function and mood, as well as on blood pressure, and inflammatory biomarkers in the blood.

What will we ask you to do?

There will be three different groups in this clinical trial. You will not have a choice which group you take part in. You will be randomly allocated to one of them for 6 months:

- Group 1 will receive support to eat a 'purple diet' that includes foods that are rich in anthocyanin content and that are convenient, tasty and affordable. Supports for Group 1 will include: regular phone contact with a dietitian, a supermarket guide, a recipe book and some limited financial aid to compensate you if you have additional food costs (A\$100.00).
- Group 2 will receive a freeze-dried anthocyanin supplement derived from blackcurrant
- Group 3 will receive a placebo product (control group). This means you will not know if whether you are taking an active or inactive supplement

Participants in all groups will be supported to take part in dietary, mood and memory assessments. All participants will also be supported in our clinics to collect samples of blood.

How will I know if I am eligible to take part?

We are inviting all adults aged 60 years and over with observed memory complaints to apply to participate in the research study. However, participants will only be recruited to the study after being assessed by a researcher via a telephone interview.

You will not be eligible to participate in this study if you have:

- Been diagnosed with any type of dementia such as Alzheimer's Disease, Parkinson's Disease or any other neurodegenerative disorder
- A history of psychiatric (other than mood) disorder in the past 5 years
- Other significant neurological history including head injury, epilepsy, or tumour.
- Have difficulty understanding English

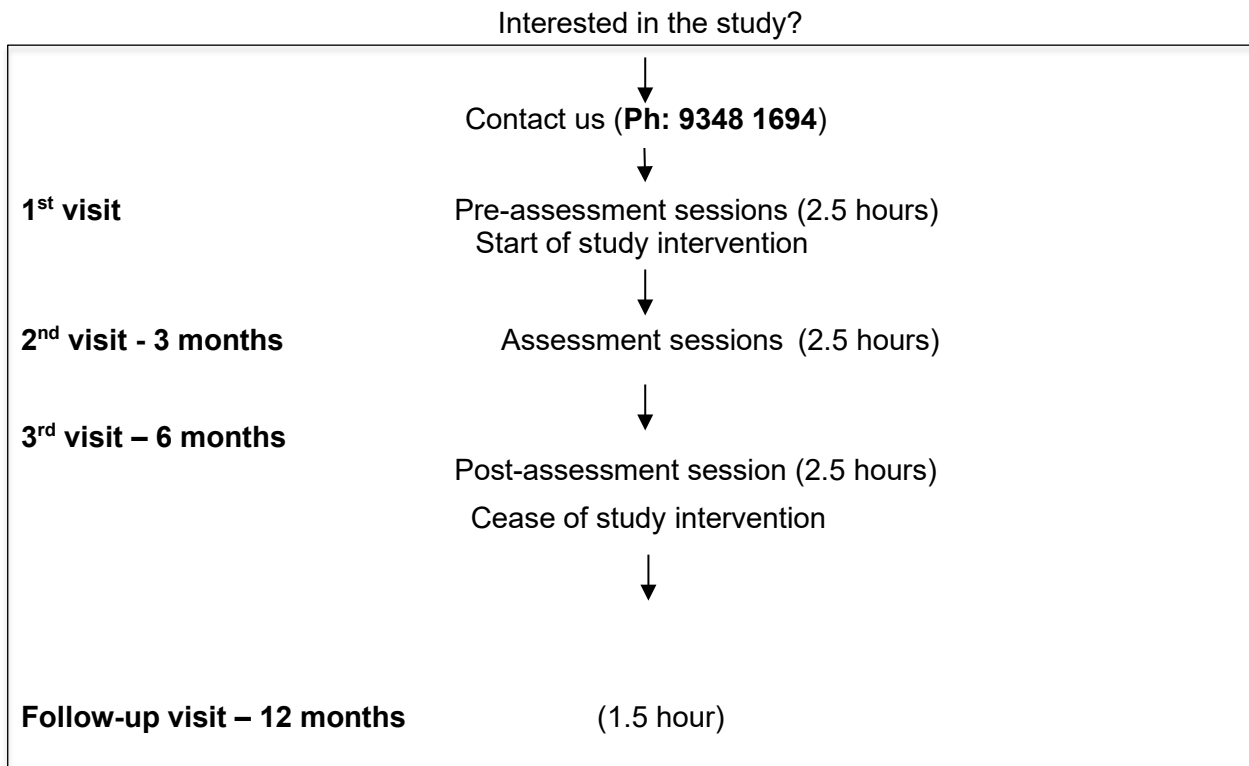
If interested, potential participants should contact the Clinical Trial Manager (Ph: 4239 4186) to enrol in the study or ask further questions.

What happens next if I am eligible to take part?

Once you have been assessed as eligible and agree to be included in the study, appointments will be arranged for you to attend three data collection sessions (baseline, 3 and 6 months) as well as a shorter 12-month follow-up session. These will occur at the Centre for Healthy Brain Ageing (CHeBA) at the University of the New South Wales. At each of the assessment sessions, we will measure/collect:

- Weight and height
- Blood pressure, using an automated blood pressure monitor.
- *Blood* samples will be taken for various laboratory analyses. Blood samples will be used to quantify inflammatory biomarkers.
- Cognition, including memory, and mood using a number of different tasks.
- Dietary habits using a computer-based app that will assist you on recording all food and drinks that you ate on three different days. This will be requested to be done before the first session, during the study and at the end of the study. A researcher will assist you on how to use this computer-based app.

A flow chart of these commitments appears below.



What are the possible inconveniencies of taking part?

Both the cognitive assessment and dietary assessment sessions are time consuming. Some participants may find the mental tests to be difficult and a little stressful, as the tests are designed to be challenging. Some slight discomfort might be caused when the blood samples are drawn by the qualified phlebotomist (nurse that takes blood samples).

- Group 1 - the ‘purple diet’ will be encouraged and instructed to consume purple fruits and vegetables in their diet for 6 months. This may be associated with some inconvenience and fatigue due to the need to both buy, cook and include new food items in their diet. These will be minimized through regular phone support and counselling from a dietitian and also through the use of a supermarket guide and new cookbook containing easy and tasty recipes. Eating more purple foods may also be associated with some financial cost depending on the type of purple foods purchased. To minimize this, participants in this group will be eligible for some financial reimbursement (financial compensation of \$100.00).
- Group 2 and 3 who receive the anthocyanin or placebo supplement will be required to consume the freeze-dried fruit product (6 g) every day for 6 months which may lead to taste fatigue. There is a small risk that participants may experience symptoms of allergies or

adverse effects from consuming the freeze-dried product in which case it is advised to see a doctor as soon as you notice any allergy symptoms.

What if I change my mind about participating?

You are free to stop the study at any time. You may also withdraw your consent for the use of your data in the study at any point if you wish. It is your choice and all of your rights will still be respected.

What will we do with the information and samples we obtain?

All information will be kept secure and identified by a code rather than by your actual name. Your actual name, and whether you are a recipient of the anthocyanin or placebo supplement will only be held by one researcher on the team, to ensure integrity of results and maintain privacy of participants. The confidentiality of all participants will be maintained, and all data will be de-identified in any published results.

Data collected from this study will be used in journal publications, presented in seminars, and form a component of the thesis of a higher degree research student and an honours student.

Privacy

Participants in Groups 2 and 3 will receive the anthocyanin or placebo supplement from a contracted third party Arepa Holdings Ltd (“Arepa”). If you are a participant in Group 2 or 3, your name and address will be disclosed by the University of Wollongong to Arepa, to enable Arepa to provide you directly with the anthocyanin or placebo supplement. Please note that Arepa is located in New Zealand and therefore may use the services of a third party distributor located in Sydney to arrange delivery of the supplement to you. Further information about Arepa’s Privacy Policy can be found: <https://drinkarepa.com/pages/terms-and-conditions>.

Further information about the University’s handling of your personal information can be found at: <https://www.uow.edu.au/privacy/>.

If at any time you have any questions, please do not hesitate to ask. Your involvement in the research is entirely voluntary. You are free to withdraw from the research at any time without penalty. If you have any enquiries regarding the conduct of the research please contact the Secretary, University of Wollongong Human Research Ethics Committee on (02) 42214457 or email rso-ethics@uow.edu.au, and quoting study number 2021/ETH12083.