**Informed Consent form for participants taking part in the Fruit juice trial**

This research will be conducted by academic staff members and a student from the School of Medicine and Health Sciences at the University of Wollongong in collaboration with the Queensland Alliance for Agriculture and Food Innovation and Agri-Science Queensland, Department of Agriculture, Fisheries and Forestry.

This research is funded by the University Global Partnership Network (UGPN)/ 2016 Grant Scheme and the fruit juice have been provided by NutraFruit.

The researchers are:

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**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the research with you)**
* **Consent Form (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form**

**PART I: Information Sheet**

**Introduction**

The above named researchers are conducting a clinical study with fruit juice with substantial amount of anthocyanins.

Anthocyanins are compounds found naturally in fruits and vegetables that provide the rich colour such as blue and deep red. These compounds possess strong antioxidant abilities which may protect the cells of the body from damage.

There is some research that associates foods and beverages that are rich in anthocyanins with a decreased risk of age-related diseases, such as cancer, cardiovascular diseaseand neurodegeneration. Considerable attention has been paid to anthocyanin in foods, in terms of their potential health benefits.

The purpose of this study is to determine the effect of fruit anthocyanin supplementation through consumption of fruit juice on blood pressure and memory and cognition in older adults diagnosed with MCI over an 8-week period.

This study will also determine if consumption of fruit juice will have any significant effect on inflammatory markers (Briefly explained as the body's response to injury or infection) and insulin sensitivity measured from blood glucose and insulin.

**Purpose of the research**

It is well known that a diet that is high in fruits and vegetables is linked to many health benefits throughout life. It is thought that some of this protective effect may be due to the flavonoid compounds (anthocyanins) found in fruits and vegetables. This study will allow scientists to have a better understanding of how these compounds work in the body and how they positively affect overall health.

**Type of Research Intervention**

This research will involve a daily consumption of either 200ml plum juice or commercially available blackcurrant cordial (control arm) for eight weeks with a 4-week washout period before crossing over to receive alternate beverage. In other words, each arm will last for eight weeks with a 4-week washout period in between. Beverages will be delivered weekly, chilled in 2x1L opaque plastic bottles.

**Participant selection**

We are inviting all adults aged 55 years and over with observed cognitive decline to participate in the research on the Queen Garnet plum juice.

People will be unable to participate if they have:

* Uncontrolled hypertension (Blood Pressure: >160/95 on day of testing)
* Dementia (any level)
* Any fruit allergies
* Type 1 (Insulin dependent) diabetes
* Any other unstable physical or mental health condition
* Have difficulty swallowing.

**Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you agreed earlier. Whatever decision you make, it won’t affect your relationship with the University of Wollongong or the Illawarra Health and Medical Research Institute (IHMRI) in any way.

**Procedures and Protocol**

At start, midway and end of each 8-week period, participants will attend the research facility following an overnight fast (22:00 onwards). 10mls of blood (equivalent of 2 tablespoons) will be collected from the arm using a syringe and needle and baseline urine samples will be collected and a standardised breakfast (cereal, milk, banana, tea/coffee) provided.

At the first visit, a questionnaire will be administered to record demographic characteristics, tobacco use, and consumption of alcohol, supplements and medications. Information on background diet will be collected using repeated 3-day food diaries and 24-hr dietary recall questionnaire. Blood and urine samples will be collected to test for inflammatory biomarkers (briefly explained as the body's response to injury or infection) as well as insulin sensitivity determined from blood insulin and glucose level.

Blood pressure will be measured using a 24h ambulatory blood pressure monitor at the beginning and end of each study arm. The ambulatory blood pressure monitors are small, lightweight battery powered units designed to take blood pressure and heart rate measurements for 24hours or longer hours.

The monitors are carried in pouches that are strapped and/or belted to the side of the participant. Blood pressure and heart rate measurements are taken using a blood pressure cuff attached to the participant’s arm. This information is recorded in the monitors and transferable.

Seven cognitive tests will be administered to asses mental functioning.

Table 1: Study events, times and requirements

|  |  |  |  |
| --- | --- | --- | --- |
| Study stages | Location | What you need to do / what will happen | Time needed |
| **Visit 1:** Sign up and baseline measurements  **Visit 2:** Week 4 (mid-way through the first arm of the study)    **Visit 3:** Week 8(conclusion of first arm of study)  **4-week washout (rest) period**  **Visit 3b:** Week 1 (Crossover to second arm of study)  **Visit 4:** Week 4 (mid-way through the second arm of the study)  **Visit 5:** Week 8 (conclusion of study) | IHMRI  IHMRI  IHMRI  Participants’ residence  IHMRI  IHMRI | -Fill out consent form and questionnaire on demographics, physical activity, tobacco and alcohol use as well as supplements and medications.  -Fill out a 24h dietary recall questionnaire and 3 day food dairy provided to record subsequent meals.  -Provide 24h urine sample from the time you arrive to the next day (sample bottles and instruction will be provided)  -Wear an ambulatory blood pressure monitor to measure blood pressure for 24hrs.  -Provide 10mls of blood sample (equivalent of 2 tablespoons) drawn from the arm.  -Anthropometric measurements taken  -Cognitive tasks administered (7)  -Provide 24h urine sample from the time you arrive to the next day (sample bottles and instruction will be provided)  -Wear an ambulatory blood pressure monitor to measure blood pressure for 24hrs.  -Provide 10mls of blood sample (equivalent of 2 tablespoons) drawn from the arm.  -Anthropometric measurements taken  -Cognitive tasks administered (7)  -Provide 24h urine sample from the time you arrive to the next day (sample bottles and instruction will be provided)  -Wear an ambulatory blood pressure monitor to measure blood pressure for 24hrs.  -Provide 10mls of blood sample (equivalent of 2 tablespoons) drawn from the arm.  -Anthropometric measurements taken  -Cognitive tasks administered (7)  Following the 4 week washout period, Participants will be provided with the second study beverage. This will be delivered to their homes.  -Provide 24h urine sample from the time you arrive to the next day (sample bottles and instruction will be provided)  -Wear an ambulatory blood pressure monitor to measure blood pressure for 24hrs.  -Provide 10mls of blood sample (equivalent of 2 tablespoons) drawn from the arm.  -Anthropometric measurements taken  -Cognitive tasks administered (7)  -Provide 24h urine sample from the time you arrive to the next day (sample bottles and instruction will be provided)  -Wear an ambulatory blood pressure monitor to measure blood pressure for 24hrs.  -Provide 10mls of blood sample (equivalent of 2 tablespoons) drawn from the arm.  -Anthropometric measurements taken  -Cognitive tasks administered (7) | 3hrs  3hrs  3 hrs  3hrs  3hrs |

**Duration**

The research takes place over 20 weeks in total. During that time, it will be necessary for you to come to the clinic 5 times over the study period and each visit will last for 3 hours. At the end of twenty weeks, the research will be finished.

**Inconveniences**

The cognitive 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).

Participants will be required to consume the same fruit juice (200 ml) every day for 8 weeks (x2), which may lead to taste fatigue and some minor inconvenience. Some participants may experience relief of constipation.

**Risks**

Participants who have any sort of fruit allergies are advised not to participate in this study. There is a possibility that participants may experience symptoms of allergies or adverse effects from consuming the juice in which case it is advised to see a doctor as soon as you notice any allergy symptoms.

**Benefits**

By participating in this research you may help researchers to improve current knowledge on the effect of consumption of anthocyanin rich foods on various domains of cognitive functioning, blood pressure, and inflammatory markers. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

**Reimbursements**

Participants of this study will be offered their individual results from the nutritional assessment that they completed in the testing process. As the individual results from the cognition assessments do not constitute a formal assessment of psychological functioning or provide diagnostic information individual feedback on cognitive performance will not be given, however, a brief report outlining the results from the whole study will be provided to participants at completion of the study. Participants will also be offered free parking at or free transport to the University of Wollongong on the day of their interviews.

**Confidentiality**

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the researchers.

**Sharing the Results**

The knowledge that we get from doing this research will be published in journal articles in order that other interested people may learn from our research. Upon request, we will make this available to the participants. Confidential information will not be shared.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

**Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the above named researchers.

Thank you for your interest in this study.

**This study has been reviewed by the Human Research Ethics Committee of the University of Wollongong. If you have any concerns or complaints regarding the way the research this research has been conducted, you can contact the Ethics Officer, on (02) 4221 4457 and quote study number HE16/278**