



PARTICIPANT INFORMATION AND CONSENT FORM

THE EFFECTS OF COFFEE BEVERAGES ON COGNITIVE FUNCTION IN A HEALTHY OLDER POPULATION

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1. Introduction

You are invited to take part in this research project. This Participant Information and Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to have the tests and treatments that are described;
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

Coffee is one of the most widely consumed beverages in the world and contains both caffeine and other compounds which may have beneficial effects on cognitive performance, cardiovascular function and mood. This study is being conducted to investigate the effects of different coffee beverages on cognitive function, mood and cardiovascular function in healthy older adults. As a way of measuring the impact of different coffee beverages, this study will compare the effects of different types of coffee beverages over a 3 month period. We will assess your performance on different cognitive tasks and cardiovascular measures before you begin consuming the coffee beverage, 1 month after consuming the coffee beverage, and 3 months after consuming the coffee beverage. You will be randomly assigned to consume one coffee beverage treatment which is either a caffeinated instant coffee, decaffeinated instant coffee or a placebo instant coffee (which has coffee flavour and taste). This research is being funded by Nestec, Switzerland. Part of this research will also be used as part of Christina Kure's doctoral course research activity.

3. What does participation in this research involve?

To be eligible to participate in this project you must:

- Be aged over 60
- Have no existing or pre-existing physical or neurological conditions
- Have no History of psychiatric, cardiac, endocrine, gastrointestinal, or bleeding disorders
- Not be taking Psychoactive medications
- Have no Clinically high blood pressure without control/treatment
- Have no History of substance abuse

- Be a non-smoker
- Have no allergy to lactose, gluten, or wheat
- Not be Currently participating or having participated in another clinical trial during the last 2 months prior to the beginning of this study
- Have no Hearing impairment
- Be a light to moderate coffee drinker (no more than 16 cups of coffee per week)
- Be willing to go without caffeine-containing foods and beverages and alcohol for 24 hours before each testing session

Participation in the study will involve attending Swinburne University's Brain Sciences Institute (BSI) on 5 separate occasions.

The BSI is located at:
 Swinburne University of Technology
 Brain Sciences Institute
 400 Burwood Rd, Hawthorn

The following outlines what you will be required to do each visit:

Visit 1 – Practice (total time 3.5 hours):

The first visit is a training session. The study will be explained to you in detail and you may ask the researchers any questions or raise any concerns that you may have about the study. During the training session you will be asked to complete a demographics and medical questionnaire, 2 short cognitive tasks and provide informed consent to participate in the study. You will then complete 4 versions of the computerised cognitive tests which you will be doing during your subsequent testing sessions. The purpose of this visit is to familiarize you with the tasks and study procedures and to reduce learning effects.

Visit 2 - Baseline Testing session (total time 3 hours):

This is the first of 2 "baseline" testing sessions. Twenty-four hours prior to each session you will be asked to avoid certain food and drinks (see Appendix 1 for list of foods to avoid). You will be asked to come in well-rested, following a normal night's sleep. During this visit, you will complete some questionnaires on your current mood as well as the computerised cognitive test battery. During this visit, a blood sample will also be taken which will be later analysed for oxidative stress and inflammation. A qualified venepuncture technician or research nurse will be collecting the blood sample. They will extract approximately 15ml of blood from a vein in your arm using a syringe. The blood samples will be sent to pathology labs for analysis as described in section 4. Your next "baseline" testing session will be 4 weeks after this session. During this 4 week period, you must not drink any coffee (caffeinated or decaffeinated) drinks. This is to ensure there are no residual effects of your regular coffee.

You will be asked if you would like to provide an additional blood sample which needs to be a fasting blood sample. This means that you need to fast from the night before and cannot eat or drink in the morning until after you have provided the blood sample. This extra blood sample is voluntary – that is, you do not have to provide this blood sample if you do not want to. You will not be penalized for not providing this extra blood sample. This blood sample needs to be taken once sometime between visits 2 and 3. This additional fasting blood sample will be used to measure essential fatty acid status which is a measure of your omega 3 and omega 6 blood levels. As it can be difficult for some people to come into the BSI, there is an option of having this blood sample taken at your local Gribbles Pathology collection centre (which is where we send the other blood to be analysed). If you prefer this option, you will be provided with a slip that you give to the Gribbles Centre and they will extract approximately 8ml of blood from a vein in your arm using a syringe, the same way the other blood is being collected. If you prefer to come into the BSI for this additional fasting blood sample, the nurse will extract approximately 8ml of blood in the same way as described in visit 2.

Visit 3 - Baseline Testing session (total time 3 hours):

After not consuming any coffee for the last 4 weeks, you will return for your second "baseline" testing session. Twenty-four hours prior to each session you will be asked to avoid certain food and drinks (see Appendix 1 for list of foods to avoid). You will be asked to come in well-rested, following a normal night's sleep. When you arrive for the session you will be given a small snack to eat (sandwich of your choice). You will complete some questionnaires on your current mood, sleep and overall well being. Then you will complete a version of the computerised cognitive tests, some pen and paper cognitive tests. During this visit, a blood sample will also be taken (described above in visit 2). Your cardiovascular function will be measured using 2 things:

- A doppler ultrasound will be used to measure the blood flow going toward your brain and within an artery in your brain. This is a quick, non-invasive measure where a small amount of water soluble gel is placed on your neck and side of your head. A pen-like probe is then placed over the gel and it will take a few minutes to get a good signal which will be recorded for 1 minute. The gel can then be removed with a tissue.
- The sphygmocor system will be used to measure the elasticity of your arteries (how quickly your arteries can expand and contract due to changing blood flow requirements). This is also a non-invasive measure where a pen-like probe is placed on your wrist and it takes a few minutes to get a good signal which will be recorded for 30 seconds.

With both of these cardiovascular measures, you will not experience anything unpleasant, and these procedures are completely pain-free. Furthermore, the cardiovascular equipment used meets the necessary Australian safety standards.

You will be randomly allocated to one of the four coffee beverage treatments.

Neither you nor the researcher will know which treatment you will be taking (double-blind study design). You will be supplied with one month's worth of coffee beverage. The coffee will be packaged into single serve portions of 3g. You will be required to have 3 cups of your allocated coffee beverage treatment per day and you may add milk and/or sugar if desired.

Visit 4 - 1 month post treatment (total time 1.5 hours):

After consuming your allocated coffee treatment for 1 month, you will return for another testing session. Twenty-four hours prior to each session you will be asked to avoid certain food and drinks (see Appendix 1 for list of foods to avoid). You will be asked to come in well-rested, following a normal night's sleep. When you arrive for the session you will be given a small snack to eat (sandwich of your choice). During this visit, you will complete some questionnaires on your mood, sleep and overall well-being as well as completing the computerised cognitive test battery. You will be given the remaining coffee beverage treatments for the next 2 months to be consumed the same way - 3 servings a day with/without milk and sugar as desired.

Visit 5 - 3 months post treatment (total time 3 hours):

After consuming your allocated coffee treatment for 3 months, you will return for your final testing session. Twenty-four hours prior to each session you will be asked to avoid certain food and drinks (see Appendix 1 for list of foods to avoid). You will be asked to come in well-rested, following a normal night's sleep. When you arrive for the session you will be given a small snack to eat (sandwich of your choice). You will complete some questionnaires on your current mood, sleep and overall well being. Then you will complete a computerised cognitive test battery as well as additional tests to measure your cardiovascular function (Doppler and sphygmocor, described above in visit 3). During this visit, a blood sample will also be taken (described above in visit 2).

You will be compensated \$250 at the end of the study for your participation.

4. What will happen to my test samples?

A blood sample will be taken on 3 occasions as part of this study – visits 2,3 and 5 (as well as an optional fasting blood sample in between visits 2 and 3). The blood will be taken by a qualified venepuncture technician or research nurse at the BSI, and stored in 2 separate containers. One container will be sent to Pathology Labs in Australia and the other will be sent to the sponsor, Nestec, in Switzerland. All samples sent to pathology labs will be non-identifiable. That is, only participant numbers will be used with respect to blood samples, not names. All samples will be analysed for markers that indicate the body has absorbed antioxidants from the coffee beverages and for measures of inflammation, stress and omega 3 and 6 status. After the samples have been analysed, they will be destroyed appropriately and therefore not used for any other research other than the current study.

You will be asked to provide additional consent for the collection of your blood during the research project in the consent form below.

5. What are the possible benefits?

We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits may include improvements in cognitive function and blood flow.

6. What are the possible risks?

The treatments in this study are coffee beverages - a drink which is consumed on a regular basis by millions of people. Additionally, all participants in this study must be regular coffee drinkers so should not experience any side effects from the coffee beverage treatments. Caffeine may have some side effects such as, dehydration (feeling thirsty), headaches, nervousness and nausea (a sick feeling). However, these side-effects are rare and if they do occur are generally very mild. People who consume very low amounts of caffeine may experience physiological effects from the caffeine dose. You will be free to withdraw from the study at any time if you feel unwell. Staff members are trained in first-aid, and in the unlikely event you do experience any discomfort or symptoms that are somewhat severe immediately contact Karen Nolidin on 9214 5472 or your local health care professional.

Having blood taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel. Rarely, there could be a minor infection or bleeding. If this happens, please inform the research nurse or your local health care professional.

7. What if new information arises during this research project?

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and decide if it affects you.

8. Can I have other treatments during this research project?

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

9. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

10. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw.

11. How will I be informed of the results of this research project?

The results of the study will be published in a peer reviewed journal and part will be used for Christina Kure's doctoral course research activity. All data will be approved by the sponsor before being published.

12. What else do I need to know?

• What will happen to information about me?

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. Investigators in possession or control of participant data that may contain personal information shall not disclose that information to anyone other than the individual concerned. Names of participants will only feature on consent forms and will not be attached to any other data on which names will be replaced by codes. Non-identifiable data relating to this study will be sent to collaborating investigators at Nestec based at Switzerland. Nestec own all information collected during this study. All information sent to Nestec will remain confidential and will only be used for the purpose of this study. During the study, the data will be kept in the possession of the investigator(s) when needed as reference, but otherwise kept locked in a secure filing cabinet at Swinburne University. Data and records relating to the study will be stored at Swinburne University and Nestec for 15 years. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

• How can I access my information?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

• What happens if I am injured as a result of participating in this research project?

If you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

The sponsor, Nestec, has agreed to provide compensation to you for any injury suffered as a result of your participation in the research project, in accordance with the Medicines Australia Guidelines for compensation for injury resulting from participating in a company-sponsored research project. A copy of the Medicines Australia Guidelines is available to you from the research staff on request.

• Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Swinburne University

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13. Consent

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.

I understand that information collected during this study could lead to commercial products or patents, and understand and agree not to disclose information regarding the study that is revealed to me throughout my participation in the study.

Participant's name (printed)

Signature Date

Name of witness to participant's signature (printed)

Signature Date

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed)

Signature Date

** A senior member of the research team must provide the explanation and provision of information concerning the research project.*

I consent to the storage and use of blood samples taken from me for use in this specific research project only as described in Section 4 of this document.

Participant's name (printed).....

Signature Date

Researcher's name.....

Signature Date

Note: All parties signing the consent section must date their own signature.

14. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher on 9214 8167 or any of the following people:

Name: ***Karen Nolidin***

Role: Research Assistant

Telephone: 9214 5472

Name: ***Marni Kras***

Role: Clinical Trials Co-ordinator

Telephone: 9214 5094

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Research Ethics Officer, Swinburne Research (H68),
Swinburne University of Technology, P O Box 218, HAWTHORN VIC 3122.
Tel (03) 9214 5218 or +61 3 9214 5218 or resethics@swin.edu.au

**Food and drink to be avoided during 24 hours
prior to every testing session.**

<u>Drinks</u> <u>AVOID:</u>	<u>Drinks that are OK</u>
<p>All types of tea (e.g. earl grey, green, black, Oolong) Drinks containing tea (ready to be consumed, instant) Herb teas Coffee Hot chocolate/Cacao/Nesquik/Milo Fruit juices: Orange juice Grape juice Apple juice All alcohol</p>	<p>Warm milk</p> <p>Cordial Lemonade Sodas Water</p>
<u>Fruits, vegetables, nuts</u> <u>AVOID:</u>	<u>Foods that are OK</u>
<p>Blackberries Green and red grapes Raspberries Strawberries Blueberries Cherries All citrus fruit such as oranges, grapefruit, lemon, lime, tangerines Plums and prunes Apples Raisins, Currants (black and red) Olives Spinach Asparagus Hazelnuts and walnuts</p>	<p>Banana Cantaloupe Pineapple Pear Carrot Pasta Rice</p> <p>Peanuts</p>

<p><u>Cereals and Breads</u> <u>AVOID:</u> Buckwheat Oats Barley Corn/Wheat Beans Lentils</p>	<p><u>Foods that are OK</u> Cereals containing rice White rice White bread White pasta</p>
<p><u>Desserts, sweets, biscuits</u> <u>AVOID:</u> Anything containing chocolate e.g. chocolate bars, chocolate, chocolate cakes, chocolate biscuits, chocolate cream, chocolate mousse, chocolate ice-cream Cereal bars Jams and frozen fruits Nutella</p>	<p><u>Foods that are OK</u> Plain yogurt Honey Butter/margarine Biscuits with no chocolate</p>
<p><u>Other</u> <u>AVOID:</u></p>	<p><u>Foods that are OK</u></p>
<p>Olive oil Grape seed oil</p>	<p>Vegetable oil, canola oil, peanut oil</p>