Chief Investigator: Dr Catherine Bondonno
Nutrition and Health Innovation Research Institute
School of Medical and Health Sciences
Edith Cowan University
270 Joondalup Drive
JOONDALUP WA 6027
Phone: 6304 4601
Email: c.bondonno@ecu.edu.au

Participant Information Letter

Project title: Wise & Well Study
Ethics Approval Number: 2023-04621-BONDONNO
Principal Investigator: Dr Catherine Bondonno

An invitation to participate in research

You are invited to participate in a project titled the **Wise & Well Study** which seeks to assess the health impacts of a diet and lifestyle behaviour change program. You are being asked to take part in this project because you are a woman aged between 60 and 80 years.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative or friend.

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 be involved in the research described;
- Consent to the use of your personal information as described.

What does my participation involve?

Your participation in this research project will involve 7 visits in total over 12 months to the RPH Research Foundation Building and the Bone Density Unit - Sir Charles Gairdner Hospital (SCGH).

To determine whether you are eligible to participate in this study, we will ask you some questions about your health and medication use on the phone (this is known as pre-screening). If you are considered eligible and are interested in participating, we will organize a physical screening visit (visit 1) and send you an information pack, including this participant information letter, an appointment letter, and a map of the venue for the first visit.

VISIT 1A

@ RPH Research Foundation

You will be asked to arrive for this visit fasting, not having had anything to eat or drink (except water) from the night before for 10-14 hours. The study will be explained to you in detail and any questions you have will be answered. You will be asked to sign a consent form if you wish to participate in the study. A consent form must be signed prior to any study assessments being performed. A copy of this consent form will be provided. We will determine your eligibility by measuring your blood pressure, height, and weight and performing an electrocardiogram. We will not conduct an electrocardiogram if your blood pressure is not within the range for eligibility. If eligible for the study, we will continue with the baseline assessments of the study:

1. A list of all current medications and supplements used.
2. A blood sample (45 mL, approximately 3 tablespoons) will be taken for the measurements of blood lipids (triglycerides/cholesterol/HDL cholesterol) and other biochemical measurements related to usual diet and disease risk.
3. Hip and Waist circumference.
4. Grip strength of your dominant arm will be performed (2-3 minutes).
5. Timed Up-and-Go (TUG) will be performed to assess mobility.

This visit will take approximately 90 minutes.

VISIT 1B

@ RPH Research Foundation

1. Cognitive Function Test training. This will be a run through of the tasks that will be used to test cognitive function, so you are familiar with the tasks and the testing procedure.

This visit will take approximately 90 minutes.

After visit 1

Following your initial clinic visit, links for online questionnaires will be sent to your email and you can complete these at home at a time convenient to you. This can be done from your desktop, laptop or on your phone. The online questionnaires usually take approximately 1 hour to complete, and they are used to collect the following information: General details such as age, gender, and marital status; Bowel health; Beverage consumption; Physical activity; Readiness to change lifestyle; Health status and quality of life; Depression and anxiety; Sleep pattern; Physical functioning and mental health; and Medication and health care use. You will also be sent a link to complete an electronic food frequency questionnaire, this questionnaire collects information about your usual food intake in the last 12 months, and it takes approximately 30-40 minutes to complete, as well as a link to complete a Short Dietary Survey, this survey is about the food you eat and the amounts that best describe your usual intake over the last month, and takes approximately 20 minutes to complete.

Note: you need to be able to complete your questionnaires online (using a computer, a laptop, or a smart phone) for you to be included in the study.

VISIT 2

@ RPH Research Foundation

At this visit cognitive function tests will be performed and you will be given a home blood pressure monitor to record your blood pressure morning and evening for seven consecutive days. This visit will take approximately 60 minutes.

After visit 2

You will be randomly assigned (that is by chance) to either the behaviour change group at the beginning of the study (if you are in the intervention group) or to the behaviour change group at 12 months (if you are in the control group). *Everyone in the study will receive the behaviour change program, only the timing of this information will differ*.

Depending on which group you are randomly assigned to the subsequent visits will be as follows:

Intervention Group	Control group
VISIT 3 @ Bone Density Unit - Sir Charles Gairdner Hospital (SCGH) Four DXA scans will be performed in total (20-30 minutes)	**VISIT 3** @ Bone Density Unit - Sir Charles Gairdner Hospital (SCGH) Four DXA scans will be performed in total (20-30 minutes)
VISIT 4 *@ RPH Research Foundation* A meeting with the Study nurse who will provide a 30-minute consultation and will discuss the behaviour change program with you.	
Via email After your baseline assessments you will receive an email with your blood pressure, fasting blood cholesterol, fasting blood glucose (sugar), BMI and the spine, hip, and whole-body bone density results. Following visit 4 you will be sent the Short Dietary Survey monthly.	*Via email* After your baseline assessments you will receive an email with your blood pressure, fasting blood cholesterol, fasting blood glucose (sugar), BMI and the spine, hip, and whole-body bone density results. Following visit 4 you will be sent the Short Dietary Survey monthly.
VISIT 5 *@ RPH Research Foundation* **3 months after visit 4** A 15-minute face-to-face consultation with the Study Nurse. Muscle function and cognitive function tests will be repeated to observe if there have been any changes over time. ***After visit 5*** Following your clinic visit, links for online questionnaires will be sent to your email and	**VISIT 4** *@ RPH Research Foundation* **3 months after visit 2** Muscle function and cognitive function tests will be repeated to observe if there have been any changes over time. ***After visit 4*** Following your clinic visit, links for online questionnaires will be sent to your email and

you can complete these at home at a time convenient to you.	you can complete these at home at a time convenient to you.
VISIT 6 *@ RPH Research Foundation* **12 months after visit 4** All baseline assessments will be repeated including the online questionnaires.	**VISIT 5** *@ RPH Research Foundation* **12 months after visit 2** All baseline assessments will be repeated including the online questionnaires.
VISIT 7 @ Bone Density Unit - Sir Charles Gairdner Hospital (SCGH) Four DXA scans will be performed in total (20-30 minutes).	**VISIT 6** @ Bone Density Unit - Sir Charles Gairdner Hospital (SCGH) Four DXA scans will be performed in total (20-30 minutes).
	VISIT 7 A meeting with the Study nurse who will provide a 30-minute consultation who will discuss the behaviour change program.

Reimbursement of study costs

A $50.00 eGift Card of your choosing will be issued on completion of the study.

Do I have to take part in this research project?

Your participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any time.

If you do decide to take part, you will be given this Participant Information Letter and Consent form to sign and you will be given a copy of the information letter to keep. Your decision to take part, or to take part and later withdraw, will not affect your relationship with the research team.

Your privacy

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All information will be stored on a password protected secured shared drive with only the study investigators having access to the data. All personal information will remain confidential. You will be assigned a unique study number. Any data disseminated will only include this study ID, to ensure confidentiality. All files will be locked in secure filing cabinets when not in use. RPH Research Foundation has electronic and key card access. Your personal information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except where requested for specific reasons, and then you will be asked to provide written consent.

In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this letter if you would like to access your information.

All data collected will be kept in accordance with ECU's Data Management Policy. Electronic data will be stored on a secure Microsoft SharePoint site provisioned by ECU's IT Services. All records will be stored as required in ECU's Records Management Policy. The data will be retained for 25 years and destroyed, if appropriate at the end of the retention period. Data will be de-identified when stored and at the end of the retention period, the data will be destroyed, if appropriate under the State Records Act.

Possible Benefits

Within 3 months following the completion of the 12-month study (randomised controlled trial) we will provide you with the results of your blood tests (triglycerides/cholesterol/HDL cholesterol and other biochemical measurements related to risk of disease), blood pressure, body composition (including body weight, bone mineral density, and body fat mass). Note, because participants will be recruited to this study over a 12-month period, and blood tests will be performed together as a batch at the same time, it may be more than 24 months before you receive this information if you are among the first participants involved in the study.

If there are measurements taken during screening, or during the study that indicate the possibility of significantly elevated risk for heart disease, you will be advised to take these to your GP for review.

In particular, the behaviour change program may lead to improved diet and lifestyle and more intensive risk factor management, with the potential to prevent future dementia, cardiovascular disease events and falls.

Possible Risks and Risk Management Plan

Possible risks and disadvantages of taking part are:

- having blood taken may cause some discomfort, bruising, nausea, or light-headedness. If this happens, it can be easily treated. To minimise this risk a butterfly needle will be used to take blood samples and you will be sitting down to avoid the risk of falling.
- measurements of blood pressure may cause mild discomfort during the inflation of the blood pressure cuff around the arm.
- in the event of an adverse reaction to any of the procedures staff at RPH Research Foundation Building are trained in first aid.
- This research study involves exposure to a very small amount of radiation when completing the DXA scans at two (2) different times over 12 months that you would not otherwise receive as part of your usual care. As part of everyday living, everyone is exposed to naturally occurring background radiation. The estimated dose due to the natural background radiation in Perth is approximately 1.5 mSv per year. The effective dose from this study will be no more than 0.1 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low.
- Answering survey questions on your physical and mental health as well as measuring your AAC score, bone density, body composition, and receiving your results, may cause anxiety related to the results and health implications. You may have significant, mild or no change in anxiety and overall quality of life. If you have any change, or are otherwise worried, please

talk with your doctor or our study coordinator who can provide guidance on available support services.

- In the case of a re-emergence of the COVID-19 pandemic, extra precautions will be taken into account to further minimise the risk of transmission. These measures include the use of appropriate personal protective equipment, sanitisation of all equipment and common surfaces, and physical distancing between research staff and participants.

Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment.

What will happen to my test samples?

The collection of blood is a mandatory component of this research project. The purpose of blood collection in this study is for measurements of factors related to vascular health such as blood lipids and biomarkers of compliance with the interventions. All blood samples will be used for the purposes of this research and future questions related to the broader objectives of this research. Stored blood samples will be individually re-identifiable (coded). Privacy and confidentiality will be maintained by using password-protected databases. Samples will be stored at the Edith Cowan University School of Medical, Health Sciences at Royal Perth Hospital Unit, until all appropriate tests are conducted.

In addition, blood samples provided will be stored for future research within the Edith Cowan University School of Medical, Health Sciences at Royal Perth Hospital Unit. The samples may only be used to investigate questions related to the broader objectives of this research. That is, research relating to the cause and prevention of disease. This may involve using samples and data collected in future studies aiming to understand factors that influence health. This will allow for the investigation of research questions that require a larger number of participants than that required for this specific research study. You will be asked to provide consent for the collection of your blood prior to the commencement of this research project.

What happens when this research study stops?

We will advise you of the outcomes via your preferred communication method (email or letter). We also intend to publish our results in research journals and present them at research conferences locally, nationally and internationally. Your name or any other identifying information will not be included in any of the publications or presentations.

Has this research been approved?

This research project has received the approval of Edith Cowan University's Human Research Ethics Committee, in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*. The approval number is 2023-04621-BONDONNO

Contacts

If you would like to discuss any aspect of this project, please contact the following people.

Chief Investigator
Dr Catherine Bondonno
Senior Research Fellow

Edith Cowan University
P: 6304 4601
F: 6304 5384
E: c.bondonno@ecu.edu.au

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

Independent Person
Research Ethics Support Officer
Edith Cowan University
P: 6304 2170
E: research.ethics@ecu.edu.au

If you wish to participate in this research, please sign the Consent Form at visit 1.

Sincerely,

Catherine Bondonno

Chief Investigator