

Participant Information and Consent Form – General (Extended)

Brain Bootcamp Frontiers

1. Introduction

You are invited to participate in a study looking at the impact of your lifestyle factors on your brain health, cognition and awareness of dementia over time.

You have been selected because you are currently aged 55 years or more, live in a rural or remote area in Australia, are able to communicate in English, and have access to the internet.

This Participant Information Form tells you about the research project and explains the assessments 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 do not understand or want to know more about. Before deciding whether you would like to take part, you may wish to talk about it with a relative or friend.

Participation in this study is entirely voluntary: you are not obliged to participate and if you decide to participate, you are free to withdraw at any time without having to give a reason and without consequence. You will not be penalised or disadvantaged in any way if you choose not to participate.

If you decide you want to take part in the research project, you will be asked to select the tick boxes next in the consent section of the online form. By clicking 'next' on the website page 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 and health information as described.

You can download a copy of this **Participant Information and Consent Form** to keep from our website.

2. What is the purpose of the study?

The purpose of this study is to identify if the Brain Bootcamp Frontiers initiative will decrease risk of dementia and increase dementia awareness and cognitive performance.



This research project is being led by researchers from Western Sydney University, Manchester University and Maastricht University. No member of the research team will receive a personal financial benefit from your involvement in this research project.



The information you share with us will help us to understand how to better target dementia awareness initiatives for older Australians in rural and remote areas.

3. What does participation in this research involve?

To participate in the study you will need to:

- Be aged 55 or older;
- Live in a rural, regional or remote area in Australia;
- Have no current diagnosis of dementia,
- Have no current diagnosis of severe depression; and
- Not be participating in any other lifestyle or brain health intervention.

This project is a **randomised waitlist-controlled trial**, which means if you decide to participate, you will be randomly allocated to one of two groups: the **Intervention group** OR the **waitlist control group** and asked to complete surveys over time. This type of study design will help us to determine how effective the intervention is. You will be able to participate in the intervention regardless of your group allocation.

Participants assigned to the **Intervention group** will complete the following steps:

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|--------|---|---|
| STEP 1 |   | Participate in online survey and cognitive telephone assessment |
| STEP 2 |  | Receive Frontiers Box delivered to door |
| STEP 3 |   | 3 months later, participate in follow-up assessments |
| STEP 4 |  | 6 months later, participate in online survey |
| STEP 5 |   | 9 months later, participate in follow-up assessments |

Participants in the **waitlist control group** will complete the following steps:

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|--------|---|--|
| STEP 1 |   | Participate in online survey and cognitive telephone assessment
[Enrolled in waitlist for 3 months]
[Do not receive brain health profile until 3 months later] |
| STEP 2 |   | 3 months later, participate in online survey and cognitive assessment |
| STEP 3 |  | Receive Frontiers Box delivered to door |
| STEP 4 |   | 3 months later, participate in follow-up assessments |
| STEP 5 |  | 6 months later, participate in online survey |
| STEP 6 |   | 9 months later, participate in follow-up assessments |

The **online survey** will ask about your demographics (e.g. age, gender, marital status, education level), dementia awareness and information about your lifestyle habits and behaviours such as alcohol consumption, mental health, cognitive and physical activity levels, social networks, sleep and hearing ability. This information will help to generate your own personalised brain profile which will be displayed on the screen at the end of each survey depending on your group allocation.



The **follow-up surveys** will be similar to the first online survey and include questions about dementia awareness and information about your lifestyle habits and behaviours. This information will help identify changes in your brain health profile.

The **Frontiers Box** will be delivered to your door for free once you have completed the survey at baseline.



It will contain your personalised brain health profile, a number of physical items, and information about healthy habits and behaviours.

The cognitive function assessment will take approximately 15-minutes and will be conducted by our researchers over the phone. Researchers will provide you with immediate feedback once you have completed the assessment.



Impact/Outcome evaluation

Once you have participated in the intervention for 12 months, you will have the opportunity to join in a 30 minute interview over the phone to share your thoughts on the program and provide suggestions for improvement.

Audio recordings will be sent to a professional transcribing service based in California where they will be transcribed and any data collected that could be used to identify you will be removed. Once transcribed, the audio file will be destroyed. Data collected during the study will be securely stored on password protected servers in Australia. Only researchers approved for this study will have access to these data. Records will be retained for 5 years from the date of the most recent publication.

4. What are the possible benefits of taking part?

Your participation in this project will help us to design effective initiatives targeting dementia awareness for older rural adults. You will also receive a personalised brain health risk profile at multiple time points to help support you make healthier lifestyle habits. You will also receive a \$20 gift card as remuneration for completing the program.

5. What are the possible risks and disadvantages of taking part?

Participation in this study and receiving your brain health profile and cognition score should not cause you any discomfort however some questions within the survey ask about mental health and depression which may be difficult for participants.

If you find anything from this study stressful or upsetting, you can stop at any time. We advise that you contact your GP.

Additionally, helplines and resources are available for you to contact below.

Lifeline: 13 11 14
Suicide call back service: 1300 659 467.
National dementia Helpline: 1800 100 500

If necessary, the research team can arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team.

6. What if I withdraw from this research project?

Taking part in this research is entirely voluntary. If you do decide to take part you can withdraw at any time without having to give a reason, without prejudice.

If you decide to withdraw from the research project, the researchers will not collect any further data on you. Data collected up until the time of withdrawal may be retained.

Please note, if at any point you feel you do not want to answer a question, or would like to move on, or wish to end the questionnaires, you may choose to do so at any time, and you do not need to give a reason.

7. What will happen to information about me?

All aspects of the project including results will be strictly confidential and only researchers with ethics approval will have access to your information. Your information will be anonymous in reports and presentations resulting from the research.

Your responses will only be disclosed with your permission, except as required by law. No individual will be identified in any publication of the results. During the study, only the research team approved by Western Sydney Human Ethics Committee will have access to the data. By agreeing to participate in the study, we are asking for unspecified consent which means your de-identified data may be used in future research (Please see Pg. 8 for more information)

A summary of the data can be made available to you on request. Please contact Laura Dodds at l.dodds@westernsydney.edu.au.

8. Complaints and compensation

If you have a complaint regarding the conduct of the research or researcher, please contact the complaints contact person. Details can be found in Section 10 of this form.

9. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Ethics Committee (Reference Number: **H15230**).

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007, updated 2018). This statement has been developed to protect the interests of people who agree to participate in human research studies.

10. Further information and who to contact

We would like to provide you with as much information as you require to consider this study.

This project is conducted by **Ms Laura Dodds**, PhD candidate at the MARCS Institute for Brain, Behaviour and Development at Western Sydney University.



If you would like further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact:

Name	Ms Laura Dodds
Position	Project Manager
Telephone	+61 474 340 463

Email	l.dodds@westernsydney.edu.au
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This project is being supervised by **Dr Joyce Siette** from the MARCS Institute for Brain, Behaviour and Development, Western Sydney University.



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

Name	Dr Joyce Siette
Telephone	+61 423 880 292
Email	joyce.siette@westernsydney.edu.au

If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the following. Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

Name	Director, Research Impact and Integrity
Telephone	02 4736 0581
Email	humanethics@westernsydney.edu.au

What will happen with my information if I agree to it being used in projects other than this one?

Thank you for considering being a participant in a University research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.

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This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.

You have been asked to agree to **Unspecified consent**

When you agree to unspecified consent it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in any future research.

To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use *will not* have information in it that makes you identifiable.

The researchers who are managing the data under this Plan will decide what types of future projects are suitable for this data to be used in. The projects may mean that the dataset is given to other researchers outside of the current research team. The researchers could also be from anywhere in the world and may, or may not, have affiliations with a University. The data will be held for a significant period of time – until it is felt that it is no longer needed for research. After this time the data will be securely destroyed.

The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.

You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>