Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Improving physical health and quality of life and reducing cognitive decline and the rate of falls for people with mild cognitive impairment: a randomised controlled trial
Short Title	Balance on the Brain
Protocol Number	*RGS0000003930*
Project Sponsor	Curtin University
Coordinating Principal Investigator/ Principal Investigator	Dr Elissa Burton
Associate Investigator(s)	Prof Keith Hill, Prof Nicola Lautenschlager, A/Prof Kathryn Ellis, Ms Meg Lowry, Prof Anne-Marie Hill, A/Prof Rachael Moorin, A/Prof Joanne McVeigh, Mrs Angela Jacques, Prof Kirk Erickson
Location	Across the community and memory clinics, adult community and allied health divisions.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have reported memory issues or been diagnosed as having mild cognitive impairment. The research project is testing a new balance and walking program for people with mild cognitive impairment to try and improve health, quality of life and reduce cognitive decline and falls.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved and what information is being collected. Knowing what is involved will help you decide if you would like 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, your local doctor or health professional (e.g. physiotherapist).

Your participation is voluntary
Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current or future medical care in any way.

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; and

- 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.

Your withdrawal from the study
You are under no obligation to participate in or continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason. You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw at a later date. If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

If you withdraw from the study, your information that has already been analysed and/or included in a publication may not be able to be withdrawn or destroyed. In such circumstances, your personal information will continue to form part of study records and results. Your privacy will continue to be protected at all times.

2 What is the purpose of this research?

The purpose of this project is to determine if we can improve the physical health and quality of life and reduce cognitive decline and the number of falls for people with mild cognitive impairment.

The total number of people who will participate is 396.

Falls amongst people with mild cognitive impairment are a high cause of injury and may cause other problems such as loss of confidence and reducing independence. Rates of falls are higher for people with mild cognitive impairment than those without mild cognitive impairment. Improving balance has been shown to reduce falls for people without cognitive impairment. However, it is unknown whether balance training and walking can help people with mild cognitive impairment to reduce falls and improve physical health.

The Balance on the Brain program that we have designed is aimed at improving quality of life and physical health and reducing cognitive decline and the number of falls. This project aims to compare the effectiveness of this program with a "usual care" group who will receive health promotion education. The project will also look at whether the Balance on the Brain program is cost effective and whether it improves the costs to the health care system associated with mild cognitive impairment.

This research has been initiated by Dr Elissa Burton at Curtin University. The research project is being funded by the National Health and Medical Research Council (NHMRC) and Curtin University.

3 What does participation in this research involve?

Participation in this project will involve answering some questions about your health and physical activity to identify whether you are eligible to participate in the study and that you meet the criteria for having mild cognitive impairment.

If you are eligible and are happy to participate in this research project a signed consent form is required prior to starting and completing any study assessments. If you agree to participate a research officer will come to your home and ask you some questions about yourself and your

health and will ask you to participate in a physical assessment, such as walking, sitting to stand and balance activities. This is expected to take around 60-90 minutes. We will also ask you to wear a small device (accelerometer) on your thigh for 7 days so that we can see how active you are. Research staff will return to your home again in around 8 days to collect the device. The same assessments will also be repeated 6 and 12 months later.

After completing these questions and assessments the first time, you will be randomly allocated (by chance) to one of two groups, the usual care group (where you will continue within your usual activities, medications and care) or the balance intervention group. Both groups will continue to receive usual care from their health providers, e.g. doctors, dentists.

The balance intervention group will be visited at home by a qualified physiotherapist who will explain what balance exercises and walking should be done over the next week. These exercises will continue to progress over 24 weeks. If you are in the balance intervention group, the physiotherapist will visit you 6 times in your home over 24 weeks and will also phone another 4 times to see how the balance and walking program is going and to answer any questions you may have or to make any necessary changes. The balance program can be done with the help of a phone or tablet (like an IPad) by downloading an App, which the physiotherapist will assist with, or if you prefer we have books and CD's that can be used also. The aim is for participants allocated to the balance group to progress over time to doing around 20-30 minutes of balance training 4-5 times a week and 30 minutes of walking 5 times a week.

All participants regardless of which group they are randomly assigned to, will be asked to complete a diary. Questions will include things like: have you had a fall, if so did you need medical help; and how much physical activity have you done this week? It is expected that this will take around 1-2 minutes to complete each day or 5-10 minutes a week. Each month we will call you and discuss what you have written in your research study diary.

The balance program will run for 24 weeks and then we will keep in contact with all participants for a further 6 months (i.e. 12 months total). The reason for staying in contacting with everyone for a further 6 months is we would like to know whether the balance program was continued after the physiotherapists finished helping or whether it was stopped. We also want to know what effect this had on physical health, quality of life and whether it reduced falls and cognition (e.g. memory, attention) or not.

At the 6 month and 12 month assessments we will ask a small number of participants from the balance program group (i.e. 20 from the 198 participating) if they would be happy to be interviewed about how they found participating in the balance and walking program, for example what they liked, what they didn't like about it. The interview is expected to take around 20-30 minutes and will happen separately to the actual assessments.

There will be no cost to you for taking part in this research project, nor will you be paid. Due to all visits taking place at home there is no requirement to travel and therefore no reimbursements required.

Record Linkage with WA Health data

If you give permission we would like to link the information we obtain about you to any other relevant information about your health in WA, such as hospital admissions or if you use community services to help you live independently. For example, rather than asking you to remember the dates and reasons for any previous admissions to hospital, we will collect this directly from computerised information that already exists. Once you have given your permission, we can do this part of the study without any direct involvement from you. We would also like to collect this information for the 12 months prior to your involvement in the study because this will allow us to compare your health before and then during involvement in the study. Again this requires no direct involvement from you.

Services Australia (formerly Department of Human Services Information)
Additionally to assist us to estimate any costs related to medical care during our research project you will also be asked to fill out and sign a separate consent form authorising the researchers to access your complete Medicare Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS) information as outlined in the consent form. Medicare collects information about your doctor visits, medical procedures and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to Services Australia who holds this information confidentially. The information you give will be used for the purposes of this project including to allow us to calculate the costs and savings that were made 12 months prior to starting your involvement in the project and for the duration of the project.
You are by no means obliged to give us access to this level of information and you can still participate in the program if you choose not to give consent to access this information.

4 What do I have to do?

If you agree to participate in this research project you will not have any restrictions placed on you. You can continue with your usual lifestyle and medical care. You will just be required to keep a diary recording your activities, and other details as outlined in this form or as advised by the research team.

5 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, we hope to see that the balance and walking program will improve physical health and quality of life and reduce cognitive decline and falls in the 6 months it is undertaken.

6 What are the possible risks and disadvantages of taking part?

This research project involves completing some physical activities as part of the assessments. These are routine assessments and the risk of taking part is minimal. Half of the participants will be randomly allocated to the balance and walking program group to participate in an individual exercise program for 24 weeks. When participating in exercise there is always a small risk of feeling side effects or experiencing an injury. The balance program has been used by over 1,500 people around the world, including people with mild cognitive impairment, stroke, Parkinson's Disease and dementia. The balance programs were developed by a physiotherapist who is on the research team and they have used these safely many times to assist their clients over the past three years. Therefore, the risks of participating are low, because we will also have a qualified physiotherapist taking you through what you need to do and they will monitor your progress six times in person and will call you a further four times during the six months. If you haven't done any exercise for a while you may experience some muscle soreness or fatigue at the beginning. This is very normal and should pass in around 2-4 days. If for some reason you feel distressed at any time during the research project it is possible to suspend or even end participation if you would like to. If so, please complete the withdrawal form. If you are advised by your doctor or a health professional to withdraw you can also do this at any time by completing the withdrawal form.

7 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the lead researcher will tell you about it and discuss with you whether you want to continue in the research project. If you decide to

withdraw, please complete the withdrawal form. If you decide to continue in the research project you may be asked to sign an updated consent form if anything has changed.

Also, on receiving new information, the lead researcher might consider it to be in your best interests to withdraw you from the research project. If this happens, she will explain the reasons and arrange for your regular health care to continue.

8 Can I have other treatments during this research project?

Yes other treatments are allowed during this research project, except participation in a drug and/or another exercise research trial. If you start any additional exercise or physical activity programs during the intervention we will ask you to document this in your diary. If you also start taking any supplements such as vitamins or minerals please also write this in your diary.
You are welcome to contact us directly if you have any questions or concerns you would like to discuss.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- the program being shown not to be effective, and
- the program being shown to work and not needing further testing.

10 What happens when the research project ends?

If you are randomly allocated to the balance and walking program you will get to keep the programs on your electronic device and/or the book. When the results of the project are available all participants who completed the research project will be given the results for the whole study group. The results will not contain any information which can identify you.

Part 2 How is the research project being conducted?

11 What will happen to information about me? (Storage, retention and destruction of your information)

By signing the consent form you consent to the research investigators and relevant research staff collecting and using personal information about you for the research project (including the phone screen data which are applicable to the main study). Any information obtained in connection with this research project that can identify you will remain confidential. We will store this information on the secure REDCap system (which is located in Australia) in a way that your identity is known (i.e. your name, post code, date of birth, medical record number, phone number). This is needed so that we do not ask you to participate in the study more than once and also so that we can contact you to make appointments or discuss your involvement in this study. Only active research staff can access this information and they require a password and then an additional passcode to access the REDCap file. Any hard copy documents (e.g. consent forms) will be stored in a locked cabinet in the locked office of the lead researcher at Curtin University.

Once data collection for this study has been completed, data will be taken from REDCap into a secure and restricted folder in the Curtin University R-Drive for analyses. Please note, your data will always remain in Australia. Only study investigators will have access to these data. All data received by Curtin University and used in the project will be de-identified (so your identity will not be known). Data collected by Curtin University research staff will be stored on a secure network (R drive) at Curtin University for 25 years. Data provided by the WA Data Linkage

Branch (e.g. hospital and emergency data) will be stored for 7 years and data from Services Australia (e.g. MBS and PBS) will be stored for 5 years after publication. After these times data will be securely destroyed in accordance with the law and specific policies of each organisation. Physical files will be securely destroyed using Class B cross-cutter shredders and secure waste bins. Your 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.

Information about you may be obtained from your health records for the purpose of this research. By signing the consent form you agree to the study team accessing your health records if they are relevant to your participation in this research project. Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data). This review may be done by an institution relevant to this Participant Information Sheet, the sponsors (NHMRC and Curtin University) or as required by law. By signing the Consent Form, you authorise release of, or access to, your confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and presented in a variety of forums. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Data will only be published on groups of people, not individuals. For interview data, the participant will be known as a study code, for example ID1.

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

12 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. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. If you are injured but it is not related to the study please write this in your monthly diary.

13 Who is organising and funding the research?

This research project is being conducted by Dr Elissa Burton, from Curtin University and is funded by the National Health and Medical Research Council (NHMRC) and Curtin University.

You will not benefit financially from your involvement in this research project even if, for example, the knowledge acquired from analysis of your data prove to be of commercial value to Curtin University. No member of the research team will receive a personal financial benefit from your involvement in this research project other than their ordinary wages.

Qualified physiotherapist, Meg Lowry developed the balance programs included in this research project and Meg is a member of the research team.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project

have been approved by the HREC of South Metropolitan Health Service, the WA Department of Health (data linkage), Services Australia and Curtin University HREC.

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

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

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 study investigator Dr Elissa Burton, Senior Research Fellow on 9266 4926 or email E.Burton@curtin.edu.au.

The details of the local site complaints person are:

Complaints contact person

Name	Manager
Position	South Metropolitan Health Service Research Support and Development Unit
Telephone	08 6152 3214
Email	smhs.rgo@health.wa.gov.au

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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	South Metropolitan Health Service Human Research Ethics Committee
HREC Executive Officer	Ethics Coordinator
Telephone	08 6152 2064
Email	smhs.hrec@health.wa.gov.au

Privacy complaints

If you have a privacy complaint about the collection, use and storage of your personal and health information contact the Office of the Australia Information Commissioner. You will be able to lodge a privacy complaint with them.

Website: *www.oaic.gov.au*
Telephone: *1300 363 992*
Email: *enquiries@oaic.gov.au*
Mail: GPO Box 5218, Sydney NSW 2001

Consent Form - *Adult providing own consent*

Title	Improving physical health and quality of life and reducing cognitive decline and the rate of falls for people with mild cognitive impairment: a randomised controlled trial
Short Title	Balance on the Brain
Protocol Number	*RGS0000003930*
Project Sponsor	Curtin University
Coordinating Principal Investigator/ Principal Investigator	Dr Elissa Burton
Associate Investigator(s)	Prof Keith Hill, Prof Nicola Lautenschlager, A/Prof Kathryn Ellis, Ms Meg Lowry, Prof Anne-Marie Hill, A/Prof Rachael Moorin, A/Prof Joanne McVeigh, Mrs Angela Jacques, Prof Kirk Erickson
Location	Across the community and memory clinics, adult community and allied health divisions.

Declaration by Participant

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand the purposes, procedures and risks of the research described in the project.
2. I give permission to the research investigators and relevant research staff collecting and using personal information about me for the research project (including the phone screen data which are applicable to the main study).
3. I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Curtin University concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.
4. It will be valuable in addition to the study data which will be collected, for additional data from the following sources to be collected. Tick the boxes below if you approve for this additional data to be collected)
   - ☐ WA Health data linkage (e.g. hospital and emergency data)
   - ☐ Service Australia data (e.g. Medicare and Pharmaceuticals (medicines).
5. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
6. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

Name of Participant (please print) _____

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.

Name of Researcher (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature. I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. You do not have to attend these follow up visits if you don't want to. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis. This is voluntary and your do not have to consent if you don't want to. You can also withdraw form the study at any time by completing the withdrawal form.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Improving physical health and quality of life and reducing cognitive decline and the rate of falls for people with mild cognitive impairment: a randomised controlled trial
Short Title	Balance on the Brain
Protocol Number	*RGS0000003930*
Project Sponsor	Curtin University
Coordinating Principal Investigator/ Principal Investigator	Dr Elissa Burton
Associate Investigator(s)	Prof Keith Hill, Prof Nicola Lautenschlager, A/Prof Kathryn Ellis, Ms Meg Lowry, Prof Anne-Marie Hill, A/Prof Rachael Moorin, A/Prof Joanne McVeigh, Mrs Angela Jacques, Prof Kirk Erickson
Location	Across the community and memory clinics, adult community and allied health divisions.

Declaration by Participant

I wish to WITHDRAW my participation in the study effective from the date below. I request that the study handles the information they have collected about me in the following way (choose one option):

☐ DESTROY all information collected about me so it can no longer be used for research except as described in point 2 below

☐ RETAIN all information collected about me so it can continue to be used for research

I understand that:
1. no further information about me will be collected for the study from the withdrawal date;
2. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw from the study will not affect my access to Health Services or Government benefits.

Name of Participant (please print) _____

Signature _____ Date _____