



A randomised clinical trial of cognitive activity for the treatment of older adults with mild Alzheimer's disease
The PACE-AD Study



PARTICIPANT INFORMATION SHEET

A collaborative study of the School of Psychiatry and Clinical Neurosciences (University of Western Australia), Royal Perth Hospital and the WA Centre for Health and Ageing

Investigators: Prof Osvaldo Almeida, Ms Mandy Vidovich & Prof Leon Flicker
School of Psychiatry and Clinical Neurosciences, RPH

Introduction

You are being invited to participate in the above study because you have been diagnosed with Alzheimer's disease (AD) or you have a partner, family member or close friend who has a diagnosis. For this study we are inviting both people with mild AD *and* someone who knows them well (referred to as a "companion") to participate together. This information sheet has been written for both the person with AD and their companion, and describes the study so that an informed decision can be made regarding participation.

Please read the following information carefully and if you would like to participate, or find out more about the study, please contact the *WA Centre for Health and Ageing* as described in the cover letter. You may wish to discuss the study with relatives, friends or your GP.

Background

Recent research has found that, in older adults, participation in mentally stimulating leisure activities is associated with improved thinking skills ('cognition') and a reduced risk of dementia. There is also mounting evidence that the rate at which cognition and some aspects of daily functioning decline in some of us as we age can be reduced by cognitive intervention strategies. In fact, a lack of leisure and mentally stimulating activities is just one of a number of potentially modifiable lifestyle factors that has recently been associated with memory decline in older adults.

Despite this new information, there are very few rigorous trials investigating the benefits of these activities for people who have been diagnosed with AD. Also, the few trials completed to date have focused on directly helping people with AD, but have not considered the potential benefits of involving the carers/companions of people with AD. The purpose of this study is to investigate whether a cognitive activity program, specifically designed for people with mild AD *and their companions*, can reduce or slow further cognitive decline and improve quality of life for people with AD. It will also investigate the benefits of this type of program to the companion.

What the study involves

If you are interested in participating in the study, the first step is to contact the *WA Centre for Health and Ageing* to arrange a **screening interview** with a member of the research team. This will be conducted by phone and will involve answering a series of questions. It will take about 20 minutes to complete. Its purpose is to determine your eligibility to participate in the study, but it will also provide you with an opportunity to ask any questions you may have.

- **Baseline visit:** If you and your companion would like to participate and the telephone screening interview indicates that you are eligible, we will invite you both to attend a baseline assessment at the RPH Memory Clinic at Mercy Hospital, Mt Lawley. We will review what the study involves, including reviewing this information sheet and answering any questions you might have, and, if you still wish to participate, we will ask you both to sign a consent form.

We will then ask you both to complete a 'baseline' assessment which will initially involve you individually completing two brief questionnaires about your thinking skills and mood.

We will then ask the participant with AD to complete a more detailed assessment of their thinking skills (attention, memory, language, planning and problem solving) and questionnaires about your leisure activities, mood and memory. This will take about 60 minutes. During this time we will also ask the companion to complete several questionnaires asking for their perspective on the thinking skills and day-to-day functioning of the person with AD, as well as their own quality of life.

- **Cognitive Activity (CA) program:** The CA program will involve learning ways to actively manage changes in thinking that occur with AD, particularly attention, memory and language skills. These sessions will be held at Mercy Hospital, Mt Lawley, will run for 90 minutes each, once a week for *six weeks* and will be conducted with groups of no more than 8 participants. There will also be about 60 minutes of home-based activities each week that will give participants the opportunity to try out new skills in the real world.

Following the completion of the six week program participants will be asked to complete 90 minutes of set home activities each week, *for a further five weeks*, before returning for one final group session in the twelfth week of the program.

Participants will be provided with a workbook to store notes, activity sheets and information pamphlets that will be provided as part of the sessions and to use as a diary to remind them of what has been covered previously and what's coming up.

The sessions will be audio-taped to ensure the program is delivered at a consistently high quality. The audio-taping is not for the purpose of observing or recording the participants.

- **Follow-up visit 1:** Once you and your companion have completed the group program to which you were randomly assigned, we will ask you to both attend a review assessment at Mercy Hospital. This will take place *within four weeks* of completing the group program and will involve repeating the same series of cognitive tests and questionnaires you completed at the baseline assessment.
- **Follow-up visit 2:** Approximately 6 months after your baseline assessments (and about 3 months after you complete the group program) we will ask you both to attend a final assessment at Mercy Hospital that will again take about 90 minutes and will be an exact repeat of the baseline assessment.

Your total attendance at the RPH Memory Clinic at Mercy Hospital will depend on which group you are randomised to and this process is described in detail below. There is also a summary of the study activities at the end of this information sheet.

Randomisation to the CA program: Following the baseline assessment, you will be randomly assigned (like tossing a coin) to **one of two Arms of the program**, which will commence within four weeks of the baseline assessment. You will have a 50 percent chance of being assigned to each Arm.

- **Arm One - Participants with AD and their Carers/Companions together**

In this arm the person with AD and their companion will attend CA sessions *together*.

- **Arm Two – Companions of people with AD alone**

In this arm the companion will attend the group CA sessions. These sessions will include up to eight people who are the companions of a person with mild AD.

The participant with AD will be asked to complete home-based activities that their companion will bring home from the sessions they have attended.

Optional DNA sub-study: In addition to determining if a cognitive activity program helps people with mild AD, we are also interested in clarifying whether genetic factors (such as apolipoprotein E (ApoE) genotype) influence participants' responses to mental stimulation. Whilst one type of ApoE gene (APoE4) has previously been associated with an increased risk of developing AD, it is well established that this gene does not cause the disease; it is simply another factor that affects the risk of developing the condition.

For this reason, we are also asking if the participant with AD would be willing to donate DNA by using a mouth swab. The genetic information will not be analysed until the very end of the study. Therefore, individual results will not be disclosed unless they are clinically relevant.

Providing a DNA sample is an **optional part of the study** and you are free to continue with the study if you prefer not to consent to the sample collection. If you agree to provide a saliva swap, you will be asked to sign a separate consent form regarding DNA sample collection and storage and we will ask you to take the saliva swap at the time of your first follow up visit.

What are the possible benefits and risks?

Overall we believe this is a safe activity that we have designed specifically for people with AD and their companions. The only foreseeable difficulties arising from participation in the study are the effects of fatigue associated with group sessions and the 90 minute assessments. You might also experience a degree of frustration or feel uncomfortable if you find any of the activities, tasks or tests challenging. These issues will be minimised by offering the opportunity for rest breaks and, should you become distressed during any of the activities, you will be able to discontinue the task or ask for extra assistance. Each of the group sessions will be delivered by a member of the research team with a background in psychology, experienced in completing assessment and education sessions with people with AD.

What are the possible benefits?

We hope that all participants will receive a degree of benefit from their participation in the study. However, we cannot predict to what degree you will benefit personally from your participation. The main benefit of the study is that we expect it will increase knowledge about the effects of continued education and mental stimulation on the cognitive functioning of older adults, including those with mild AD and those who know them well.

What happens if something goes wrong, or I suffer an injury, during the study?

In the unlikely event that you suffer an adverse event or a medical accident during this study, arising from your participation in the study, you will be offered all full and necessary treatment by RPH. The Ethics Committee has approved this study on the basis (amongst others) that the reported risk of such an event is either small or acceptable in terms of the risk you face as a result of your current illness or the benefit that is possible with the new treatment being tested. No provisions have been made in this trial to offer participants who suffer an adverse reaction monetary compensation, but the absence of such a provision does not remove your rights to seek compensation under common law.

Privacy and confidentiality

All information provided by you and gathered during the course of the study will be held in strict confidence and handled in a way that is consistent with the provisions of the Privacy Act 1988. Your information will be stored in a locked filing cabinet at RPH. The information will not have your name on it and will be identified by a special study code number only. Your name will not appear on trial documents and only duly authorised persons will have access to your data. Your name will not appear on any document or publication.

Cost of participation in the trial

Participation in the trial will be at no cost to you. Reimbursement for some travel costs will be offered.

Your participation

Participation in this study is voluntary. You do not have to participate and, if you do agree to participate, you are free to withdraw at any time without explanation. If you choose not to participate, or decide to withdraw during the study, this will not affect any future medical treatment you might require at RPH in any way. Please note that if your companion withdraws from the study for any reason, this will mean that you will also have to withdraw.

Further Information

Further information may be obtained from the Chief Investigator, Professor Osvaldo Almeida, or Co-Investigator Mandy Vidovich, on (08) 9224 2855.

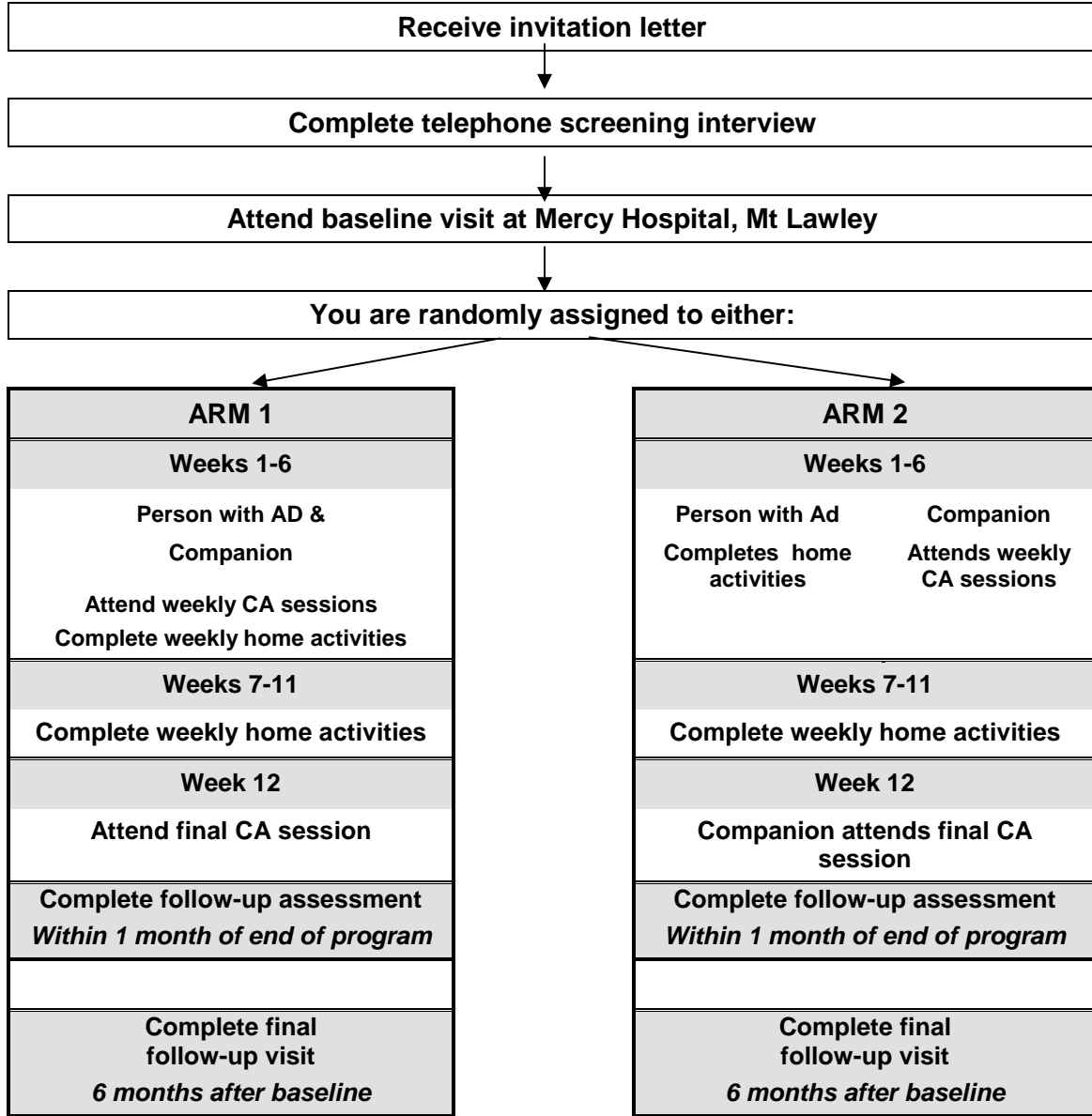
This study has been approved by the RPH Ethics Committee. If you have any questions about the conduct of the study or your rights as a research participant, please contact the Chairman of the RPH Ethics Committee, Professor Frank van Bockxmeer on (08) 9224 2244, and quote the Ethics Committee approval number EC 2009/041.



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PARTICIPATION SUMMARY





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CONSENT FORM

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I,.....agree to participate in the above study. I have read and understood the *Participant Information Sheet* and I have been given a copy of it. I have been given the opportunity to ask questions about the study and these questions have been answered to my satisfaction. I understand that I may withdraw from the study at any time without affecting any future medical treatment.

I have been advised as to what data is being collected, what the purpose is and what will be done with the data upon completion of the research. I understand that research data gathered for the study may be published and that my name or other identifying information will not be used.

Signed.....

Date.....

Signature of Investigator.....

Date.....