THE UNIVERSITY OF SYDNEY

**Exercise, Health and Performance Faculty Research Group**
**Discipline of Exercise and Sports Science**
**Faculty of Health Sciences**

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HOM*e*Care: Caring for the Dementia Caregiver and their Loved One via the HOM*e*Care Exercise and Mindfulness for Health Program

**PARTICIPANT INFORMATION STATEMENT**

**Caregiver**

## (1) What is this study about?

You are invited to take part in a research study for dementia caregivers and the people they care for. This trial aims to use computer-based platform to help Dementia Caregivers care for people living with dementia. This will be done by providing you, the caregiver, with a Mindfulness program for 12 weeks. 'Mindfulness' is a mental state achieved by focusing one's awareness on the present moment, while calmly acknowledging and accepting one's feelings and thoughts, which helps to reduce stress and anxiety. A 8-week exercise program will also be provided for the person you are caring for. We anticipate that the Mindfulness program will improve your overall wellbeing. We are also hopeful that the exercise program will improve the physical function, mobility and mental well-being in the person you are caring for, allowing for a greater independence in daily living and successful ageing-in-place, and reducing some of the burden placed on you as the caregiver.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the study. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is completely voluntary.

By giving your consent to take part in this study you are telling us that you:
✓ Understand what you have read.

- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

## (2) Who is running the study?

The study is being carried out by the following researchers:

- Professor Maria Fiatarone Singh (University of Sydney)
- Professor Sharon Naismith (University of Sydney)
- Dr Milena Simic (University of Sydney)
- Dr Yorgi Mavros (University of Sydney)
- Mr Michael Inskip (University of Sydney)
- Mr Kenneth Daniel (University of Sydney)

## (3) What will the study involve for me?

Overall, the study will require a 14-week commitment. This will include an assessment at the start of the study (week 1), a 12-week study period (weeks 2 to 13), phone based follow ups at week 4 and 8, and an assessment the end of the study (week 14).

If you agree to participate in the study, after review of this Participant Information Statement with our staff and signing of the Consent form in our clinic at the University of Sydney, you and the person you care for will undergo an assessment at this same clinic to determine if you are eligible. The visit may take between 4 to 6 hours. Once this is completed, you will be randomised, like the toss of a coin, to one of two groups.

1. Group 1 will receive an iPad which will be used for an 8-week Mindfulness program. This will be supplemented by a 8-week exercise program for the person you care for (12 weeks total). You will continue with the Mindfulness program during the 8-week exercise period. You will also be asked to help with the delivery of the exercise program to your loved one. The exercise program will be monitored remotely, with weekly video calls using FaceTime on the iPad.

2. Group 2 will be placed on a waiting list, and will be provided access to all the information and educational materials at the end of the 12-week period.

You will have your wellbeing re-assessed over the phone at 4 weeks and 8 weeks, and in clinic after the 12-week period. All tests will be repeated at the end of the study, and you will be required to attend the University of Sydney to repeat the clinic visit. The person you care for will also have assessments repeated at 12-weeks, and so will be required to attend these assessments with you.

<u>Clinic Assessments</u>

As mentioned, you will be required to attend the University of Sydney for a clinic visit before starting of the program, and again at the end of the program (at 12 weeks). During this time, the person you care for will also be assessed and so will be required to attend with you. In addition to your assessments, we may ask for your assistance with the assessment of the person you are caring for. For these clinic visits, we will assist with arranging for community transport services for seniors provided you are eligible for these services. On these visits, the following assessments will occur:

Assessment of your sleep and physical activity levels
You will be fitted with 2 monitors to measure how well you sleep and how much activity you do in the daytime over 7 days and nights. One monitor (like a wristwatch) will be worn on your wrist. Another small, slim monitor (about the size of a watch face and weighing only 100 g), will be taped on your lower back so that you will not feel it lying down or while moving about. It is waterproof and sweat-proof, so that you can shower without removing it, although you cannot take a bath or swim with it on. You will be asked to keep a log of your sleep times, including naps you take during the day. These monitors do not pose any risk to you, other than the possibility of some slight skin irritation from the tape residue over the monitor. We will ensure that the tape is applied neatly and without tensing the skin to minimise any discomfort due to the tape application. We will also place two identical monitors on the person you care for, and ask you to keep a log of his/her sleep times and naps as well.

We will ask you to return the monitors either by mail or in-person. We will provide you with a postage paid envelope to cover any associated cost.

Questionnaires
At the beginning and end of the study, you will be required to fill out some questionnaires. These relate to your overall mental health and wellbeing. We may also ask you some questions about the person you care for also.

Intervention

Group 1
Group 1 will receive an iPad, which they will be shown how to use. A website has been created that contains all the training material for both the Mindfulness and exercise programs. Each participant will have his/her own unique login. First, you will complete the 8-week Mindfulness course. The course has 8 modules, with 1 module to be completed each week. We will ask that you log that you have completed the training sessions as you do them each week on the iPad.

Before your loved one starts exercise at week 4 and once you completed week 8 of the mindfulness course, your health status will be re-assessed. You will then continue with a specialised Mindfulness course for dementia caregivers. Before your loved one starts exercise at week 4, a member of our team will come to your home. They will show you, and the person you care for, how he/she can exercise effectively and safely within your home environment. The exercise will be a combination of balance exercises, as well as strengthening exercises using resistance bands, dumbbells, and ankle cuffs. The iPad will

contain pictures and videos of the exercises that you can use as a guide. A weekly 1-hour video conference call using FaceTime will be organised, so you can discuss the progress of the exercise, and tell us and show us if you are experiencing any difficulty. We will ask you to show us the progress the person you care for is making with their exercise during this video call. We will provide you with sufficient internet access, so this will not be at any cost to you. The purpose of the exercise is to provide the necessary strength and balance required to improve walking ability, lower risk of falling, and ultimately support the goal of ageing-in-place. We also hope that this will reduce any distress you may experience as a caregiver, and reduce your physical stress and potential for injuries from lifting. While the exercise program isn't designed for you specifically, we will ask you to help your loved one complete the exercise program. This may include demonstrating the exercise, assisting with performance the exercise or putting on ankle weights, and providing encouragement and instruction to do it safely and effectively. At the end of the program, we will ask that you return the iPad. If you have internet access at home, you will still be able to use the HOM*e*Care website to continue the program. After the 16-week intervention is complete, the health status of you, and the person you care for, will be re-assessed.

Group 2

Group 2 will be placed on a waiting list for 12 weeks. After this point, you will be provided access to the HOM*e*Care website where you can access all the training materials that were provided to Group 1. We will also arrange 1 home visit to show you how you can exercise safely within your home environment. However, there will not be any access to the trainer using FaceTime. Your health status will be re-assessed 4 weeks, 8 weeks, and again at the end of the program, together with the person you care for.

**(4) How much of my time will the study take?**

The total time required for this part of the study is 14 weeks, or around 3.5 months. This includes the initial clinic visit, the 8-week Mindfulness intervention, the 8-week exercise program for the person you care for and your final assessment. If you are randomised to Group 1, you will be asked to complete the initial 8-week Mindfulness course, which can take 15- 30 minutes per day, and then continue this Mindfulness practice over the next 4 weeks. After week 4 of the mindfulness program, a home visit be scheduled for our staff to show you how you can help the person you care for exercise safely and effectively within your home. We will ask that you facilitate the exercise program for the person you care for. We will encourage that the exercise program be performed 3 days per week, and may take between 45 to 60 minutes to do. The time spent on the exercise can be broken down into smaller periods (e.g., 4 x 15min sessions per day), or spread out over 5 days, to ease burden and minimise fatigue. In addition, a 1-hour FaceTime session will be organised every week for the 8-week exercise intervention, to discuss and monitor progress, and troubleshoot any concerns or problems you may have.

**(5) Who can take part in the study?**

The population we would like to study in our trial are caregivers who are living with, and are the primary caregivers of people who have dementia.

To be eligible for this study, you must meet the following criteria:

- The person you care for must have a diagnosis of dementia
- You must be willing to partake in the full study period, including the Mindfulness course and facilitation of the 16-week exercise intervention

Reasons why you may not be eligible for this study include:

- You are unable to understand or speak English well enough to understand the Mindfulness or exercise program, or to see the videos and read the materials on the iPad.
- You have major unstable medical conditions limiting your ability to exercise, or assist the person you care for to exercise safely.

**(6) Do I have to be in the study? Can I withdraw from the study once I've started?**

Participation in this study is completely voluntary and you do not have to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from your medical practitioner, your relationship with professional staff, or your relationship with The University of Sydney. You are free to withdraw at any time. If you do decide to take part you will then be asked to sign this consent form and return it to the site coordinator. Alternatively, you can do this by contacting *Professor Maria Fiatarone Singh on 9351 9755*

If your health, or the health of the person you care for, were to deteriorate to a point where the study geriatrician (Prof. Fiatarone Singh) deems your participation in study unsafe, we would inform your doctor immediately, and would need to withdraw your participation in our study.

**(7) Are there any risks or costs associated with being in the study?**

*There are risks associated with your involvement in this part of the study:*

Risk of injury: It is possible, but not likely, that facilitating the exercise program for the person you care for may cause injury to either of you. This is highly unlikely with the type of exercise that we are proposing, and the home visit and FaceTime monitoring is designed so that we can maximise your safety. We will show you how the exercises can be performed effectively and safely within your home, to minimise the risk of injury.

Potential emotional distress: Some of the questionnaires we ask you about your emotions, quality and satisfaction with life, and stress may make either of you upset or uncomfortable. Answering these questions is voluntary.

Direct costs or expenses: The Mindfulness and exercise interventions, testing and physician screen will not incur any expense for either of you. The only costs we foresee you incurring are those relating to your travel to and from the University of Sydney. If you choose to drive, we will provide you with free parking. You will both be provided a free meal during the clinic visit. We will not be able to reimburse you for the cost of commuting to the University campus. We will however assist you with arranging free community transport for clinic visits if

it is available and you are eligible.

**(8) What happens if I suffer injury or complications as a result of the study?**

If you, or the person you care for suffer any injuries or complications as a result of this study, you should contact the study doctor (Professor Maria Fiatarone Singh) as soon as possible, who will assist you in arranging appropriate medical treatment.

If either of you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact the University of Sydney Human Research Ethics Committee.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

**(9) Are there any benefits associated with being in the study?**

By participating in this study, it is anticipated that the Mindfulness program will improve your overall mental wellbeing as a caregiver. We also anticipate that the exercise program will improve the functional independence of the person you care for. This may reduce the overall burden on you as their caregiver. There is however no guarantee that this will occur.

**(10) What will happen to information about me that is collected during the study?**

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the University of Sydney will have your name removed so that you cannot be identified. All information will be stored securely, and only the research team will have access to the information. 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.

The information about you, with your name removed, will be kept in a central, secure location in case we want to do further analysis in the future. Ethical approval will be sought first before the current information is used in future research. If you choose to withdraw from the study at any time, the information already collected will be used by the researchers, unless you ask us to have this information destroyed.

Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise. Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study finding may be published, but you will not be individually identified in these publications

During the assessments and FaceTime sessions, we will record information and data on paper, or using electronic forms. These data will be captured using an iPad. We will not be taking any video, photo or audio recordings during these assessments or FaceTime consultations. FaceTime consultations will not be recorded. All data collected will remain confidential.

The information we collect will be stored in hardcopy in locked filing cabinets at the Cumberland campus of the University of Sydney in a secure location, digitally in files located on a secure university server, as well as being entered into an electronic database that is located on a computer in the University of Sydney. This database is protected and the risk of a breach of confidentiality is extremely low. We will also protect your anonymity by assigning you a study ID Code. The data we collect will be stored for a minimum of 20 years as is the standard for data collected in clinical trials.

The only personnel that will be able to access your data directly will be the researchers involved with the HOM*e*Care trial as listed at the start of this document. If necessary, we may request medical information from you GP or specialist regarding your suitability and eligibility to participate in this testing, and may share information related to your testing results with your GP or specialist if that information may improve knowledge relating to your medical care. Your permission will be sought prior to contacting you GP or specialist.

The information we collect for this study may published in scientific journals, or presented at international conferences. No identifying information will be used in these publications or presentations.

We may ask to photograph or video record some of the exercise sessions for educational purposes. In this case, extra written informed consent will be obtained prior to the collection of these photo or video recordings. Participation in this is completely voluntary. You can refuse to be photographed or have a video recording, and refusal will not affect your involvement in the study or your relationship with the investigators or the university. You will be allowed to view and approve the photos and/or videos prior to their use. If you do consent to be photographed or have a video recording, and change your mind, you can let us know of your decision and we will destroy the images and/or videos.

**(11) What will happen to my treatment when the study is finished?**

Upon completion of the study, you will still have access to all the training materials on the HOM*e*Care website. You will not however be allowed to keep the iPads or the exercise equipment. If you were in the waitlist control group, a home visit can be arranged to teach you how to exercise safely within your home, and to show you how to use the HOM*e*Care website if you have suitable internet access.

***(12)*** **Can I tell other people about the study?**

Yes, you are welcome to tell other people about the study.

**(13) What if I would like further information about the study?**

When you have read this information, the study investigator will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Professor Maria Fiatarone Singh on her office phone 9531 9755 for further information and leave a detailed message with your name, contact details and query.

**(14) Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by *ticking the relevant box on the consent form.* This feedback will be in the form of *a one-*

*page lay summary.* You will receive this feedback after the study is finished.

Any results specific to your assessment that may assist in improving the knowledge of your condition for the purposes of your healthcare treatment will be passed onto your GP or specialist and will be discussed with you and your caregiver if appropriate.

**(15) What if I have a complaint or any concerns about the study?**

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney *2016/795.* As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- Telephone: +61 2 8627 8176
- Email: ro.humanethics@sydney.edu.au
- Fax: +61 2 8627 8177 (Facsimile)

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*This information sheet is for you to keep*