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

Person with Dementia

(1) What is this study about?

You are invited to take part in a research study for people with dementia, and their caregivers. This trial aims to use a computer-based program to help people living with dementia, as well as their caregivers. This will be done by providing you with a home-based exercise program that your caregiver will help you do. Your caregiver will also be given an 8-week mindfulness program. 'Mindfulness' is a mental state in which you focus on the present moment, while calmly accepting one's feelings and thoughts, which helps to reduce stress and anxiety. We anticipate that the exercise program will improve your physical and mental wellbeing, function and walking ability, so that you can have greater independence and fewer falls. We also hope that the Mindfulness program, and the improvement you get from the exercise, will help your caregiver care for you, while improving their energy level and sleep patterns.

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 with your caregiver, and ask questions about anything that you don't understand or want to know more about. We encourage you to discuss this information with your caregiver, and make sure you are both satisfied and happy to take part.

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 a clinic visit at the start of the study (week 1), a a 12-week study period (weeks 2 to 13), and a clinic visit at 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. During the first 8 weeks, your caregiver will take part in the Mindfulness program. After the first 4 weeks, your caregiver will continue with the Mindfulness program, and you will take part in a 8-week exercise program. Your caregiver will be asked to help you do the exercises. The exercise program will be monitored, with weekly video calls with your trainer.

2. Group 2 will be asked to wait, and will be provided all the information and materials at the end of the 14-week period.

You will have your health and wellbeing assessed at the beginning, week 4, week 8, and at the completion of the study (14 weeks). You will be required to attend the University of Sydney, with your caregiver, for the final clinic visit at week 14.

<u>Clinic Assessments</u>

As mentioned, you will be required to attend the University of Sydney for a clinic before starting the program, after 8 weeks, and again at the end of the program. Your caregiver will be present for all of these tests to assist if needed. 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;

Physician examination:
You will have a medical history and physical examination by study geriatrician and lead investigator Professor Maria Fiatarone Singh, MD before any other testing. Information we gather from this screening and the subsequent visits may be used to contact your GP to assist with your medical care both within and outside of the study.

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. Your caregiver 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 ask your caregiver 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
You will be asked to answer some questions. These relate to your overall health. Your caregiver may be able to assist with some of these questions, but some of them will require you to answer.

Tests of memory and thinking:
We will assess your overall thinking ability, language, ability and speed of decision-making, and ability to solve problems and to think about information you see. These tests may include looking at pictures and words on the computer screen, and will require you to touch the screen to respond. You may be required to read words, or remember pictures and repeat them. You will also do some tests using a pen and paper, and may be asked to write or draw items, or answer questions verbally.

Physical tasks: These tests are a series of quick assessments that look at a range of physical abilities including how quickly you can walk, your ability to rise from a chair 5 times, balance while standing in different positions and while walking, and walk while performing some thinking tasks. You will be able to rest as much as needed in between each test.

Assessment of strength
Your peak muscle strength will be measured. For this test, increasingly heavier weights are adjusted by the examiner at 1-minute intervals until you fail twice at a given load on different machines, which usually requires 8-10 tries. Strength will be tested on weight lifting machines under direct supervision by a skilled assessor. Both your upper body and lower body strength will be tested. Prof Fiatarone Singh will first make sure it is safe for you to be tested, and each test will be stopped if you experience any pain or ask to stop, or the assessor determines the test should be ended.

Assessment of walking ability

Your walking ability will be determined by measuring how far you can walk in 6 minutes. You will be asked to walk around a room or up and down a hallway, using any aid you need such as a stick or a frame, if you normally use one. You will be closely followed by a team member so that we can measure the distance you walk. You will be allowed to stop if you need a rest.'

Body fat and muscle mass:

Measurements of your body weight, height, waist circumference, body fat, and muscle mass will be taken. The measurements of fat and muscle will be done by passing a small electric current through your body that is too small to feel and poses no risk to you at all, called bioelectrical impedance analysis. If you have a pacemaker, you will not undergo this test. There are no other risks or contraindications to the testing.

Nutritional assessment:

We will ask your caregiver a brief questionnaire about what you eat and your eating habits.

Blood pressure:

Resting pulse and blood pressure while you are lying, sitting and standing for 2 minutes

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. First, your caregiver will complete the 8-week Mindfulness course. Once your caregiver has completed the week 4 of the 8-week course, a member of our team will come to your home. We will show you and your caregiver how you 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. Your caregiver will continue with the Mindfulness program during this time also. A weekly 1-hour video phone call will be organised with your caregiver, so that you can both discuss the progress of the exercise, and tell us and show us if you are experiencing any difficulty. We will also ask to observe you doing the exercises during this video call, so that we can determine the progress you are making, and so that we can make some recommendations if necessary. We will provide you with internet access, so this will not be at any cost to you. The purpose of the exercise is to improve your strength and balance so that your walking and movements in and out of chairs is easier, you are less likely to fall, and require less help for daily activities. 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 8-week exercise program is complete, we will re-check the health of you and your caregiver.

Group 2

Group 2 will be asked to wait 12 weeks. We will re-check your health at 4, 8 and 12 weeks. After this point, you will be provided all the training materials that were provided to Group 1. We will also arrange one home visit to show you how you can exercise safely within your home. However, there will not be any access to the trainer after this.

(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 exercise program and your final clinic visits. If you are randomised to Group 1, we will encourage that you exercise 3 days per week, for about 45 to 60 minutes each time. The time spent on the exercise can be broken down into smaller periods (e.g., 4 x 15-min sessions per day), or spread out over 5 days, to make it easier. In addition, a 1-hour video phone call will be organised every week for the 8-week exercise intervention, to 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 people who are living with dementia, and are living with the people who care for them.

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

- you must have a diagnosis of dementia
- Require assistance with some daily activities, and have a family member or friend who provides most of this assistance
- Be willing to partake in the full study period, including the 8-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 exercise program or see the pictures or videos of the exercises
- You have major unstable or progressive medical conditions limiting your ability to exercise

(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 and your caregiver 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?

Muscle Soreness and Injury

As with any exercise testing, there are possible risks of injury or a heart attack. The weight lifting may cause some muscle soreness and fatigue when you first start. There is also a small risk of soreness or injury during walking, chair standing and similar tests, however this is very rare during the kind of testing we use. You will be closely supervised by a trained and experienced health professional during all testing. To minimise these risks, we will carefully screen you and monitor you throughout the testing to maximise your safety.

It is possible that the exercise program may cause injury to either you, or your caregiver. This is highly unlikely with the type of exercise that we are proposing, and the home visit and phone call monitoring is designed so that we can maximise your safety. We will show you how the exercises can be performed safely within your home, to reduce the risk of injury.

Potential distress: Some of the questionnaires we ask you about your emotions, 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 are 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.

Adverse Effects

During each test procedure, and weekly throughout the program, we will ask you to inform us of any side effects that you may experience. It is important that you contact the study staff immediately if you have any unusual health experiences, injury or bad effects, whether or not you believe that the problem is related to the program or from some other cause. Prior to any testing, the study doctor will review your medical history to make sure that you are medically ready for the study procedures.

In the event of an injury or significant change in health, we will advise your GP, and may recommend evaluation or treatment in consultation with your GP as necessary. In the event of any adverse effect you will be able to contact the principal investigator Prof. Maria Fiatarone Singh at the School of Exercise and Sport Science, University of Sydney on 9351-9755.

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

If you or your carer 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 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 exercise program will improve your overall ability to carry out daily activities. We also anticipate that the Mindfulness program will improve the overall wellbeing of your 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. We will not be taking any video, photo or audio recordings during these assessments or phone call consultations. Video phone call 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 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 *protocol no. 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)

This information sheet is for you to keep