

Plain Language Statement

School of Medicine, Dentistry and Health Sciences
Department of Psychiatry
Academic Unit for Psychiatry of Old Age



Project: The EXCEL Study (EXercise for Cognitive hEaLth)

Responsible Researcher: Prof Nicola Lautenschlager

Tel: 03 8387 2326 Email: nicolatl@unimelb.edu.au

Additional Researchers:

Associate Investigators: A/Prof Kathryn Ellis, Dr Terence Chong, Dr Brett Coulson, Dr Eleanor Curran, Dr Francine Moss, Dr Victoria Palmer, Dr Tom Rego, Dr Emily You

Research Assistants: Ms Rhoda Lai, Ms Rebecca Moorhead, Ms Jenny Southam, Ms Diana Velasquez Reyes, Ms Alissa Westphal

External Advisors: Prof Kaarin Anstey, Prof Kay Cox, Dr Sam Mancuso

Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

What is this research about?

Physical activity (PA) is recommended for middle and older aged people, as it supports the health of the body and the brain. The brain health benefits of PA appear to include reducing dementia risk and supporting what is called cognition – the ability to remember, think, and plan. Middle and older aged people who experience low mood, anxiety or stress are more likely to experience problems with cognition and other health problems that might benefit from physical activity. Low mood, anxiety and stress themselves can all also benefit from physical activity.

National guidelines for physical activity have been developed. There are specific guidelines for middle and older aged people who don't have any problems with cognition and for people who experience some problems with cognition but do not have dementia, for example, people with Mild Cognitive Impairment (MCI) and Subjective Cognitive Decline (SCD). MCI is considered the stage between normal cognition and

dementia, and SCD is considered a person's experience of cognitive issues (which may or may not be reflected in formal assessments).

The increased use of information and communication technology (ICT), such as video chat programs, among middle and older aged people can be used to help people to take up physical activity. This might benefit people who wouldn't usually be able to access similar help face-to-face. This is especially important in the current context of the coronavirus (COVID-19) pandemic and increased social isolation.

The main aim of this study will be to trial a personalised 12-week home-based physical activity intervention, using ICT, to help middle aged and older people who experience memory concerns and troubles with low mood, anxiety or stress to meet physical activity guidelines.

What will I be asked to do?

Screening and Consent

If you are interested in this project, you will be invited to read this plain language statement and sign a consent form online. You will then be directed to answer a few preliminary questions to see if the study is a good fit for you. If you are unable to access the online forms and surveys, instructions on how to return the signed consent form via email or mail and who to contact with questions will also be provided.

If you agree to participate, and the study is a good fit for you based on the preliminary questions, you will be invited to take part in a screening call by phone or ZOOM with a researcher. In the screening call, the researcher will talk more about the project, what your participation will involve and re-confirm your consent to participate in this study. After that, you will be asked some further questions about yourself to make sure that the study is suitable for you. These questions will ask about your memory and concentration, your mental health, how you feel about your lifestyle, activities and physical health about. We anticipate the screening call will take about 20-30 minutes.

If this study is not suitable for you or you decide that you do not want to participate, then your involvement in this research project will end at this point.

Since the study involves carrying out physical activity at home, if this study is suitable for you, it may require some safety considerations. For this reason we will send your general practitioner (GP) a brief letter informing them of your participation in this study. If you have any health concerns that you are worried about and that you think may place you at increased risk while undertaking moderate intensity physical activity, we will recommend that you seek advice from your GP before commencing the intervention.

Physical Activity Intervention

In the week after your screening call, you will be asked to complete an online assessment survey. This survey will include demographic questions, as well as questions about your mood, health and lifestyle. You will also be asked to repeat this survey at the end of the intervention to look at how the PA program may have impacted these areas. There will be options to complete this survey in hard copy or with a researcher if the online form is not accessible to you. The survey will take around 35-45 minutes to complete.

Once you have completed the survey, an introductory session with a research team member will be scheduled (over the phone or video chat). Prior to this session, the study's PA specialist will review your responses to the screening and assessment survey questions and create a 12-week physical activity program taking your current physical activity level, health and skills into account. The research team member will take you through this personalised PA program in the introductory session. The researcher will also ask some questions about any barriers you may experience in starting or maintaining PA currently. The researcher will aim to work with you, across the 12-week PA program, to find helpful strategies that may break down some these barriers. Instructions, program plans and other resources for the 12-week intervention will be emailed to you at this time. If you have any further questions, a brief check-in, either by email or phone, can be arranged with the researcher prior to starting the PA program. Exercise equipment will be provided, as needed, to help with motivation. Equipment may include dumbbells, resistance bands and/or activity monitors. We expect this introductory session to take about 50-60 minutes.

One of the resources provided to you will be a simple physical activity diary to be completed throughout the 12-week PA program. The PA diary will be available online or as a hard copy. You will be asked to record the time you spent in each activity session. It will take 1-2 minutes to complete per session to complete the diary. A very short (5 minute) online questionnaire will also be sent to you in weeks 4, 8 and 12 of the intervention, which will ask about your mood and levels of stress.

During the 12-week PA program you will receive fortnightly contact (either via ZOOM, phone or video chat) from a research team member who will provide support, motivation and advice as needed. These catch-ups will be a chance for you to ask questions about your program, make adjustments as required and continue to work together through any barriers that may be impacting your ability to keep up with the program. The researcher will book the dates for these catch-ups at your introductory session. We expect these catch-ups to take between 5-20 minutes.

The final week 12 catch-up will be a summary of the intervention and a chance to provide you with resources to continue the PA program on your own if you would like. You will be asked to repeat the online assessment survey, as noted above, and will also be asked to complete a short evaluation questionnaire. The questionnaire will ask about

your experience of the program and any ideas you might have to improve the program for the future. You can complete the questionnaire online with the assessment survey or with the researcher in the week 12 catchup.

What are the possible benefits?

We cannot guarantee or promise that you or others will receive any benefits from this research, however, you may experience potential personal benefits including improved cognitive, physical and mental health from increasing physical activity. You may also keep any exercise equipment that is provided to you, which may include dumbbells, resistance bands, and/or activity monitors, after completing at least 8 weeks of the program.

This study may help support a greater understanding of the acceptability of physical activity programs for middle aged and older people who experience memory concerns as well as low mood, anxiety and/or stress.

What are the possible risks?

There may be some minimal risk associated with participation in physical activity, such as fatigue, shortness of breath or muscle soreness. In rare cases, you may experience dizziness, heart problems or a fall. This risk will be minimised by introducing activities gradually and in a way that is appropriate for you, and by having your GP notified of your participation in this study.

You may find participating in the questionnaires tiresome or feel stressed by answering some questions. You will be able to complete the questionnaires in several sessions or take breaks as needed.

There may be additional risks that the researchers do not expect or do not know about.

Tell a member of the research team immediately about any new or unusual symptoms that you may experience.

Please be aware that any opinions or other information related to the project that you share during the project activities will be kept confidential. If you are experiencing distress or other symptoms that the research team are concerned may place you at risk, they may suggest that you see your GP or ask for your permission to contact your GP about this. If the research team has serious concerns, they may need to make a referral for further health care support. This referral may be made even if you do not provide consent.

Do I have to take part?

No. Participation is completely voluntary. You are able to withdraw at any time. Your decision whether to take part, not to take part, or withdraw will not affect your relationship with the investigators or the organisations involved.

If you do decide to take part, you can download a copy of this plain language statement and a copy of the consent form to keep.

If you do withdraw your consent during the research project, the research team will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You are free to ask that information about you is taken out of the study, however, you should be aware that data collected by the research team that has already been used to contribute to study findings for the whole group, up to the time you withdraw, cannot be removed. Any information that has not yet been used in this way can be removed at your request.

Will I hear about the results of this project?

A newsletter describing the findings will be made available to participants. It may take up to 12 months after the last participant has completed all the study assessments to finalise the results.

What will happen to information about me?

By providing informed consent, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will be de-identified (coded). This means you will be assigned a unique study ID number that will appear on all your paperwork and online surveys/forms. Your de-identified information will be kept in locked filing cabinets or password protected computer files. All ZOOM video and phone calls will be password protected to increase the security of the call. This means that you will be provided with a unique password and you will need to enter this password prior to joining the call. Your identifiable 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.

Your name and address may be shared with a third-party sports equipment supplier in the instance that certain items you require (e.g. dumbbells) need to be mailed directly to you from the stockist themselves. In this case, the research team will notify you when this happens and which store your details will be shared with.

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, except with your permission. The results will usually be presented in a group rather than individually. Any individual results will be described without using any identifying details such as names or position titles. The knowledge and de-identified data gathered from this study may also inform similar follow-up studies in the future.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected about you 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 Research Co-ordinator, Rebecca Moorhead, if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored for at least 5 years after the publication of any results. It will be disclosed only with your permission, or as required by law.

Who is funding this project?

This research has been initiated by the study doctor, Professor Nicola Lautenschlager, and is funded by a Melbourne Academic Centre for Health grant, supplied by the National Health and Medical Research Council.

Where can I get further information?

If you would like more information about the project, please contact the researchers below:

Research Co-ordinator

Rebecca Moorhead:

Tel: 03 8344 1879 (opt.3) Email: rmoorhead@unimelb.edu.au

Responsible Researcher

Prof Nicola Lautenschlager

Tel: 03 8387 2326 Email: nicolatl@unimelb.edu.au

Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.

Who can I talk to if I experience low moods, anxiety or stress?

If you are experiencing these symptoms, we recommend you contact your general practitioner (GP). Your GP can talk to you about whether you might benefit from some treatment or support for this.

You can also contact lifeline for further support: 13 11 14