

Participant Information Statement

Research study: Active Women Over 50 randomised controlled trial

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1. What is this study about?

We are conducting research to evaluate a new program aimed at supporting women aged 50 and over to be more physically active. To do this, we will measure how effective the *Active Women over 50* program is at increasing women's physical activity over six months.

You have been invited to take part in this research because you are a woman aged 50 years or older, who lives in New South Wales, and you responded to an advertisement from our research team or community partners.

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

2. Who is running the study?

The lead researchers are:

- **Professor Anne Tiedemann**, Professor of Physical Activity and Health, Faculty of Medicine and Health, University of Sydney
- **Professor Catherine Sherrington**, Senior Principal Research Fellow, Faculty of Medicine and Health, University of Sydney
- **A/Prof Leanne Hassett**, Principal Research Fellow, Faculty of Medicine and Health, University of Sydney
- **Professor Philayrath Phongsavan**, Professor of Public Health, Faculty of Medicine and Health, University of Sydney
- **Dr Abby Haynes**, Research Fellow, Faculty of Medicine and Health, University of Sydney
- **Dr Marina de Barros Pinheiro**, NHMRC Early Career Fellow and Senior Research Fellow, Faculty of Medicine and Health, University of Sydney
- **Dr Dominika Kwasnicka**, Senior Research Fellow, Digital Health School of Population and Global Health, University of Melbourne
- **Professor Nehmat Houssami**, NHMRC Investigator (Leader) Fellow, Faculty of Medicine and Health, The University of Sydney
- **A/Prof Simon Rosenbaum**, Academic Exercise Physiologist Discipline of Psychiatry and Mental Health, University of New South Wales
- **A/Prof Georgina Luscombe**, Associate Professor of Rural Health, Faculty of Medicine and Health, University of Sydney

- **Dr Heidi Gilchrist**, Early Career Researcher and Lecturer, Faculty of Medicine and Health, University of Sydney
- **Ms Geraldine Wallbank**, Early Career Researcher and PhD Candidate, Faculty of Medicine and Health, University of Sydney

This study is funded through a competitive research grant funding from the Medical Research Future Fund (Australia Government, Department of Health and Aged Care) and the investigators declare no duality or conflict of interest.

3. Who can take part in the study?

You can take part in this research if you are a woman aged 50 years and over, live in the community in New South Wales, currently do less than 150 minutes of moderate-intensity physical activity each week and you would like to have support to be more active.

You cannot take part in this research if you do not have the English language skills necessary to complete forms and take part in conversations about physical activity, or you do not have access to the internet, or you have a medical condition that prevents you from taking part in regular physical activity, or you have a cognitive impairment or neurological condition such as motor neurone disease or Parkinson's disease.

4. What will the study involve for me?

If you decide to take part in this research, you will be asked to:

- Register your interest by completing an online form with your details. You will be contacted by the research team to assess your eligibility.
- Complete a consent form online, or paper if you prefer, if you are assessed as eligible to take part by the research team. They will provide you with the consent form.
- Complete the evaluation measures at two time points as described below.
- Set your physical activity goals for the next six months with one of our health coaches.

Group Allocation

To determine the effect of the *Active Women over 50* program (described below), everyone will be allocated to one of two groups: the *intervention group* who will take part in the program straightaway, and the *control group* who will be put on a waiting list to take part in the program in six months' time. You will be allocated randomly to either the intervention group or the control group.

Intervention group

If you are allocated to the intervention group, you will receive immediate access to the *Active Women over 50* program for six months. You will be provided a handbook that outlines the program and how to get started. You also will be asked to complete the evaluation measures described below.

Control group

If you are allocated to the control group you will not receive the *Active Women over 50* program for six months, but you will still be required to complete the evaluation measures described below. After completion of the evaluation measures at six months, you will be able to access the same *Active Women over 50* program that the intervention group received.

Active Women over 50 program

The *Active Women over 50* program includes four components: health coaching, email or SMS motivational messages, access to a website and access to a private Facebook group.

Health Coaching

You will be offered two health coaching sessions lasting up to 60 minutes each. The sessions will be offered by telephone or videoconference (e.g., Zoom) as preferred. Your health coaching session will be provided by a qualified physiotherapist who has experience in delivering physical activity behaviour change coaching. The health coach's role is to work in partnership with you to understand your needs and preferences to support you to develop a physical activity plan with achievable goals. The first health coaching session will take place at the beginning of the program and the second session will take place approximately four weeks later.

Email or SMS motivational messages

Motivational messages will be sent to you over the 6-month program. These messages aim to provide actionable plans, inspire and support your physical activity. You can choose how you receive these messages, either email or SMS text, and how often you receive them. Email messages can be sent weekly (24 emails), fortnightly (12 emails), or monthly (6 emails), and SMS messages can be sent 3 times/week (72 messages), 2 times/week (48 messages), or once/week (24 messages).

Website

Over the 6-month program you will have access to the *Active Women over 50* website. This website contains resources and evidence-based information about the benefits of physical activity to maintain health and prevent disability in older age. It also provides information on how to be active, goal setting, tips for increasing your activity, physical activity options for your location, links to existing podcasts, frequently asked questions, and inspirational videos of how other women have managed to increase their physical activity.

Private Facebook Group

When you start the program, you will have access to a private, moderated Facebook group. The Facebook group aims to connect women in the program to provide social support and inspiration for being physically active. Joining this Facebook group is optional.

Evaluation measures for all participants

Everyone who takes part in this research will be asked to complete evaluation measures at two time points, at the start of the research and six months later.

Questionnaires

If you agree to take part in this research you will be asked to complete two questionnaires about your general health, medical conditions, physical activity, any falls, mental wellbeing, physical function, and quality of life. These questionnaires need be completed at the start of the study and repeated six months later. The questionnaires will take about 20 minutes to complete each time and can be filled out electronically (a link emailed to you) or in paper format (mailed to you). If the questionnaires are not returned, you will be telephoned by a research assistant to collect this information. To reduce the risk of bias, the research team member who collects the questionnaire information will not know which group you have been allocated to.

Impressions questionnaire

To evaluate the enjoyment and effectiveness of the *Active Women over 50* program the intervention group will complete an additional questionnaire at the end of the program. This questionnaire will take no longer than 10 minutes to complete and will ask you to tell us about your experience of the *Active Women over 50* program.

Monthly health diary

All study participants will be asked to complete monthly health diaries containing questions on whether you have seen any health professionals or experienced any adverse events such as a fall. The diaries can be filled out electronically (a link emailed to you) or in paper format (mailed to you). If diaries are not returned, you will be telephoned by a research assistant to collect this information. To reduce the risk of bias, the research team member who collects the monthly health diaries will not know which group you have been allocated to.

Actigraph activity monitor

Everyone who takes part in this research will be asked to wear a matchbox-sized device called an Actigraph for seven days at the start of the program and then again six months later. You can wear the Actigraph on a belt around your waist or on your wrist. It will measure the amount of physical activity you do while wearing it. The Actigraph will be posted to you with clear instructions for use and telephone support will be available. You will be given pre-paid envelopes to return the devices to the research centre.

Evaluation interviews

To evaluate the experience of the *Active Women over 50* program, approximately 30 participants will be invited to take part in a semi-structured interview after the 6-month program. The interview will be conducted over the telephone by a researcher who is not involved in delivering the program and they will generally last 30 to 40 minutes. We will ask for your consent to audio record the interview prior to the commencement of the interview. The interview will cover your views on the advantages and disadvantages of the program, motivation, confidence, beliefs about

physical activity and facilitators and barriers to participation in each component of the program. This interview is optional.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting the research team at sph.activewomen@sydney.edu.au or call (02) 8627 6389.

If you decide to withdraw from the study, we will not collect any further information from you. Any information that we have already collected, however, will be kept in our study records and may be included in the study results. If you choose to withdraw, your decision will not have any impact on your current or future relationship with the researchers at the University of Sydney or any other organisations associated with this study.

If you take part in an individual interview, you are free to stop at any stage and you may refuse to answer any questions that you do not want to answer. You can ask for your interview data to be withdrawn by telling the interviewing researcher, or by contacting the research team at sph.activewomen@sydney.edu.au or call (02) 8627 6389. If the data has already been published, we will not be able to withdraw your data.

6. Are there any risks or costs?

While the risks involved with participation in this research are low, there is a slight chance that you may experience muscle soreness when you start a new physical activity program. This risk is taken into consideration by the researchers involved who are experienced with assessing physical activity capabilities and safety precautions advised are consistent with current clinical practice. If you suffer any injuries or complications as a result of this study, you should contact the research team as soon as possible, who will assist you in arranging appropriate medical treatment.

There is a slight risk that you may become distressed or concerned by some questions, however, you have the right not to answer any questions in the questionnaires or interviews and leave the response blank.

The intervention includes health coaching, tailored advice, and goal-setting approaches. Health coaching employs a motivational interviewing approach that acknowledges any barriers you may have to becoming more active, explores the confidence you have about being more physically active and develops individualised strategies that can be implemented. If you happen to experience distress during health coaching, the health professional can refer you back to your GP if required or to support services such as Beyond Blue (telephone: 1300 22 4636) or Lifeline (telephone: 13 11 14).

The overall cost of time to complete the study components is approximately 20 minutes for each questionnaire (one at baseline and one 6 months later), 5 to 10 minutes for each of the six monthly health diaries, 2 hours total for the health coaching calls, and wearing of the Actigraph activity monitor for at least 10 hours each day over a 7-day period at the

start of the program and again six months later. If you are allocated to the intervention group, there is an additional 10 minutes to complete the impressions questionnaire. If you choose to participate in the interview, this is an additional 30 to 40 minutes of your time.

There are no financial costs in participating in the *Active Women over 50* study nor will you be financially reimbursed for your time.

7. Are there any benefits?

While we intend for this research to build knowledge and improve physical activity levels of women over 50 in the future, we cannot guarantee that you will receive any direct benefits from participating in this study. If the results show a positive effect, the study has the potential to benefit the broader community through the provision of future programs to larger numbers of people in other settings.

8. What will happen to the information that is collected?

By providing your consent, you agree to us gathering information about you for the purposes of this study. Your information will be gathered through an online screening form survey, questionnaires, and maybe an audio recording from your participation in an interview, if you choose to be interviewed. Any information you share with us will be stored securely on password protected databases.

Audio recordings will be used for analysis purposes only. Transcription of the audio recordings will be completed by REV professional transcription service. The audio recordings will be stored on the University of Sydney password protected central research data store network. When ready for transcription, the audio recordings will be transcribed by REV and stored on REV's secure database in the United States of America while being transcribed. Once transcribed, the audio recordings will be destroyed, and the transcription will be stored on the University of Sydney password protected central research data store network.

Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Identifiable information will be only disclosed with your permission, unless we are required by law to disclose material. We anticipate study findings will be published, but you will not be individually identifiable in these publications.

Sharing research data is important for advancing knowledge and innovation. A de-identified set of the data collected in this study may be made available for use in future research. At no time will identifiable data be shared or used without your additional consent. By providing your consent you are allowing us to use your information in future projects. We do not know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

9. What happens when the study ends?

Access to the *Active Women over 50* program (health coaching, text message/emails) will cease at the conclusion of the study, but you will still have access to the website and private Facebook group. As part of the study, you will receive advice about being physically active that you can continue to use beyond the study.

10. Will I be told the results of the study?

You have a right to receive feedback of the overall results of this study. If you wish to receive a summary of the study findings, please tick the relevant box on the consent form.

11. What if I would like further information?

After reading this information, researchers at the University of Sydney 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, please feel free to contact them.

- **Call** (02) 8627 6242
- **Email** the research team at sph.activewomen@sydney.edu.au.

12. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [Protocol No: 2023/803] in accordance with the *National Statement on Ethical Conduct in Human Research (2007)*.

If you have any concerns about the study's procedures or would like to make a complaint to someone not involved in the study, please contact the University:

Human Ethics Manager

human.ethics@sydney.edu.au

+61 2 8627 8176

This information is for you to keep.