Active Women over 50: An effectiveness implementation randomised controlled trial.

Protocol

Version Number 4

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CONFIDENTIAL

STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).[1]

TABLE OF CONTENTS

PROTOCOL SYNOPSIS

Title	**Active Women over 50: an effectiveness implementation randomised controlled trial**
Objectives	Primary: To evaluate the effectiveness of the Active Women over 50 program on daily steps at 6 months compared with waitlist control among women aged 50+ years. Secondary: (1) To evaluate the effectiveness of the Active Women over 50 program on physical activity participation, falls, mental wellbeing, physical function, quality of life, sleep, bodily pain, menopause symptoms, balance, fear of falling, action planning and coping planning at 6 months after randomisation; (2) to evaluate the effectiveness of the Active Women over 50 program on goal attainment at 6 months after randomisation; (3) to evaluate the proportion of participants who i) achieve light physical activity and lower limit MVPA/week; ii) increase their daily steps by 2000+ from baseline to 6 months after randomisation; (4) to explore the experiences of participants in the Active Women over 50 program and to investigate contextual factors that affect the program uptake and maintenance; (5) to evaluate the cost-effectiveness, implementation potential, and determinants to guide scale-up; (6) to test secondary implementation outcomes (reach, fidelity and adoption, dose, sustainability); (7) To evaluate the number of daily steps for intervention participants 6 months after the program has ended, at 12 months after randomisation; (8) to evaluate the effect of the Active Women over 50 program on physical activity, falls, mental wellbeing, physical function, quality of life, sleep, bodily pain, menopause symptoms, balance, fear of falling, action planning, and coping planning for intervention participants 6 months after the program has ended, at 12 months after randomisation; (9) to evaluate the proportion of intervention participants who i) achieve light physical activity and lower limit MVPA/week, ii) increase their daily steps by 2000+ from 6 to 12 months after randomisation.
Study Design	We will conduct a two-arm parallel pragmatic hybrid type I effectiveness-implementation randomised controlled trial.
Planned Sample Size	1000 women aged 50 years and over.
Selection Criteria	Inclusion criteria: Eligible participants will be women aged 50 years and over, who are community-dwelling residents in NSW, not currently meeting the physical activity guidelines, have access to an internet connected device and who want to receive support to be more active.

	Exclusion criteria: People will be excluded if they have limited English language skills, have a medical condition that precludes participation in regular physical activity, have cognitive impairment (Memory Impairment Screen [MIS]<5), have a progressive neurological disease, or are unable to leave the house independently or walk 10 metres unassisted.
Study Procedures	Trial participants will be recruited via advertisements in community newsletters, websites and mainstream and social media, and through research volunteer registries, community organisations and health promotion services targeting women. After telephone screening for eligibility and upon giving informed consent, participants will complete a baseline survey including questions about general health and surveys related to secondary outcomes. They will wear an accelerometer device (ActiGraph) over 7 days to determine their baseline physical activity including average daily step count. They will then be randomly allocated to either the intervention group, (n=500), or a waitlist control group, (n=500). Participants will complete a similar survey at 6 months post-randomisation and will wear the accelerometer again at 6 months post-randomisation for 7 days to determine end of program daily step countand physical activity. . Intervention participants will be invited to extend their participation in the study for a further 6 months to complete a similar survey and wear the accelerometer again at 12-months post-randomisation to determine daily step count and physical activity maintenance. Completion of this extra follow-up will be optional. The intervention group will receive access to Active Women over 50 program, which includes telephone health coaching, email or SMS motivational messages incorporating several behaviour change techniques (BCTs), a program-specific website and a private Facebook page to support their physical activity. The control group will be waitlisted to receive the Active Women over 50 program after completing all 6-month follow-up measures.
Statistical Procedures **Analysis Plan** **Sample Size**	**Analysis Plan** The primary outcome will be analysed using generalised linear regression to assess the effect of group allocation at 6 and 12 months, with its corresponding baseline score as a covariate. Continuous secondary outcomes will be analysed using linear regression, adjusting for the corresponding baseline measure of the outcome variable as appropriate. We will use log-binomial regression to determine the between-group difference in the proportion of people increasing daily steps by 2000+. Fall rates will be analysed using negative binomial regression models to estimate the difference in rates between groups after 6 months. There

	will also be pre-defined subgroup analyses included by age, number of medical conditions and baseline fall history. **Sample size:** A sample size of 1000 people will provide 90% power to detect a between-group difference of 1000 steps/day (SD 4200), assuming 25% dropouts, alpha 5%. The sample size calculation was undertaken using the sampsi command in Stata.
Duration of the study	We aim to recruit all participants between December 2023 and December 2025 and complete follow-up by June 2026. Data analysis and report writing will be completed by December 2026.

1. STUDY MANAGEMENT

1.1 Principal Investigator

Name	Professor Anne Tiedemann
Position	Sydney Robinson Fellow, Professor of Physical Activity and Health School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	anne.tiedemann@sydney.edu.au

Name	Professor Catherine Sherrington
Position	Professor School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	cathie.sherrington@sydney.edu.au

Name	Assoc/Prof Leanne Hassett
Position	Senior Research Fellow School of Health Sciences, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia; Implementation Science Academy, Sydney Health Partners, Sydney, Australia.
Address	The University of Sydney
Email	Leanne.hassett@sydney.edu.au

Name	Professor Philayrath Phongsavan
Position	Professor of Public Health (Disease Prevention and Health Promotion) Director, Prevention Research Collaboration School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
Address	The University of Sydney
Email	philayrath.phongsavan@sydney.edu.au

Name	Dr Abby Haynes
Position	Research Fellow School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	abby.haynes@sydney.edu.au

Name	Dr Marina de Barros Pinheiro
Position	NHMRC Early Career Fellow / Senior Research Fellow School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	marina.pinheiro@sydney.edu.au

Name	Dr Dominika Kwasnicka
Position	Senior Research Fellow Digital Health School of Population and Global Health
Address	The University of Melbourne
Email	dom.kwasnicka@unimelb.edu.au

Name	Professor Nehmat Houssami
Position	Professor of Public Health School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
Address	The University of Sydney
Email	nehmat.houssami@sydney.edu.au

Name	Assoc/ Professor Simon Rosenbaum
Position	Senior Research Fellow Discipline of Psychiatry and Mental Health
Address	The University of New South Wales
Email	s.rosenbaum@unsw.edu.au

Name	Ms Geraldine Wallbank
Position	Early career researcher and PhD candidate School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	geraldine.wallbank@sydney.edu.au

Name	Dr Heidi Gilchrist
Position	Early career researcher and lecturer School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	heidi.gilchrist@sydney.edu.au

Name	Assoc/ Professor Georgina Luscombe
Position	Associate Professor School of Rural Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
Address	The University of Sydney
Email	georgina.luscombe@sydney.edu.au

1.2 Associate Investigators

Name	Dr Grace McKeon
Position	Postdoctoral Research Fellow Faculty of Medicine and Health
Address	The University of New South Wales
Email	g.mckeon@unsw.edu.au

Name	Prof Kirsten Howard
Position	Professor of Health Economics School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
Address	The University of Sydney
Email	kirsten.howard@sydney.edu.au

Name	Emer Prof Adrian Bauman
Position	Emeritus Professor of Physical Activity and Health School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
Address	The University of Sydney
Email	adrian.bauman@sydney.edu.au

Name	Susan Linney
Position	Consumer advisor
Email	sue.linney@innovationforce.com.au

Name	Trish Stabback
Position	Consumer advisor Country Women's Association of New South Wales (CWA NSW)
Email	paulandtrish@hotmail.com

Name	Kamilla Haufort
Position	Consumer advisor COTA NSW
Email	kamilla.haufort@cotansw.com.au

Name	Dr Karen Lee
Position	Research Fellow School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia
Address	The University of Sydney
Email	Karen.c.lee@sydney.edu.au

1.3 Statistician

Name	Raaj Kishore Biswas
Position	Biostatistician Clinical Research Centre
Address	Sydney Local Health District
Email	RaajKishore.Biswas@health.nsw.gov.au

1.4 Research Team

Name	Dr Juliana Souza De Oliveira
Position	Project Manager School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	juliana.oliveira@sydney.edu.au

Name	Ms Sandra O'Rourke
Position	Project Trial Coordinator School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	sandra.orourke@sydney.edu.au

Name	Ms Courtney West
Position	Research Officer School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	courtney.west@sydney.edu.au

Name	Ms Shannon Colley
Position	Research Assistant School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	shannon.colley@sydney.edu.au

Name	Ms Giane Caon Camara
Position	Research Assistant School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	giane.caoncamara@sydney.edu.au

Name	Ms Susan Bowman
Position	Research Assistant School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	susan.bowman@sydney.edu.au

Name	Ms Catherine Kirkham
Position	Research Physiotherapist -Health Coach School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	catherine.kirkham@sydney.edu.au

Name	Ms Elisabeth Ramsay
Position	Research Physiotherapist -Health Coach School of Public Health, Faculty of Medicine and Health, University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
Address	The University of Sydney
Email	betty.ramsay@sydney.edu.au

1.5 Internal Trial Committees

The Steering Committee is responsible for study conception, design, protocol refinement, fund procurement and providing the scientific direction of the study. The Steering Committee will ensure that the research is carried out in accordance with national guidelines on the conduct of research in humans.

1.6 Sponsor

The University of Sydney.

1.7 Funding and resources

The study is being funded through the Medical Research Future Fund Effective Treatments and Therapies grant (MRF2023710) and Medical Research Future Fund Dementia Ageing and Aged Care Mission grant (MRF2024387).

2. INTRODUCTION AND BACKGROUND

2.1 Background Information

Physical inactivity is a significant public health concern in Australia. Australian national guidelines recommend that adults should undertake at least 150 minutes of moderate to vigorous intensity physical activity per week plus muscle strengthening activities twice a week.[2] Despite the clear physical and mental health benefits of physical activity,[3] as few as 13% of Australian women aged 45-64 years meet both the physical activity and strength guidelines.[4] Alarmingly, the annual cost of physical inactivity has been estimated to be a staggering $805 million in Australia,[5] including direct costs (healthcare expenditure) and indirect costs (lost productivity).

Middle age is a crucial time for physical activity. Middle-aged and older adults are a priority group for targeted physical activity programs, since physical capacity starts to decline at around age 50,[6] and older people are generally the most inactive.[7] Regular physical activity in younger years delays age-related decline in physical capacity and disability in women aged 70+ by up to 15 years.[8] Mid-life physical activity is particularly relevant because it is also associated with a higher likelihood of being physically active in older age and reduces the risk of falls, several chronic conditions and cancers,[9,10] and increases recovery after an acute event.[11] Moreover, physical activity commenced in middle-age years (40–65 years) can reduce the all-cause risk for mortality irrespective of past physical activity levels[12] or the intensity of physical activity.[13]

Women in middle age have unique barriers to being active, such as multiple caring responsibilities and the onset of chronic conditions, yet very few evidence-based, low-cost, scalable approaches to physical activity aim to reach a large proportion of them. For example, in Australia, women comprise 47% of the Australian labour force[14] and compared to men, they juggle employment with higher primary carer responsibilities: 69% of carers aged 45–64 years are women.[15]

Moreover, 62% of women in this age group live with at least one chronic condition.[7] There are personal, cultural and structural barriers to physical activity for women in this age group. The onset of menopause can bring physical changes (such as hot flushes, weight gain and fatigue) that are barriers to being active. Women may be aware of the benefits physical activity can have on these symptoms and bodily changes but may perceive negative attitudes while exercising in public.[16] Women in regional and remote areas may face additional barriers due to geography and access to physical activity opportunities and services. [4] The competing demands and specific barriers to exercise that middle-aged women experience necessitate targeted support to encourage the adoption and maintenance of regular physical activity for healthy ageing.

Our previous systematic review demonstrates the beneficial effects of health coaching.[17] Health coaching had a small, statistically significant effect on physical activity. However, there was no evidence of an effect of health coaching on mobility, quality of life, and mood, suggesting that, to address all project objectives, health coaching should be combined with other approaches, such as online information provision, or social support. Health promotion interventions that aim to change lifestyle behaviours, which are delivered by digital technologies, offer an efficient, effective, and scalable solution for preventing noncommunicable diseases[18] and addressing physical inactivity. Community members are now generally savvy digital service users thanks to COVID-19. The virtual, technology-driven design of this research supports rapid, implementation nationwide, including rural/regional Australia, and helps address the time challenges experienced by many women due to competing pressures.

We developed and pilot-tested the Active Women over 50 program among 62 women aged 50+ years. Our pilot process and impact evaluation results demonstrated high acceptability and uptake. The intervention participants increased daily steps from baseline by 2000+ steps (OR 6.31, 95%CI: 1.22 to 32.70), and increased their overall physical activity levels (light, moderate, and vigorous intensities) more than controls.[19] The high uptake, engagement, positive recommendation (87% would

recommend to others), and promising impact on physical activity provided evidence and justification to conduct a larger trial.

2.2 Research Questions

1) Does the Active Women over 50 program increase daily steps in women aged 50+ years compared to waitlist control?

2) Does the Active Women over 50 program improve physical activity, mental wellbeing, physical function, quality of life, sleep, balance, action planning, and coping planning, and reduce bodily pain, menopause symptoms, fear of falling, and falls compared to waitlist control?

3) What are the participant's experiences of the Active Women over 50 program? What are the contextual factors that affect the program uptake and maintenance?

4) What is the cost-effectiveness of the Active Women over 50 program compared to waitlist control?

5) Is there potential for the Active Women over 50 program to be implemented and scaled up? What are the characteristics of implementation that would support scale up and sustainability?

6) What is the impact of the Active Women over 50 program on physical activity and other secondary outcomes 6 months after the program ending?

2.3 Rationale for Current Study

Regular physical activity in younger years delays disability in women aged 70+ by up to 15 years, yet participation is sub-optimal. Mid-life physical activity is also associated with a higher likelihood of being physically active in older age. Women in middle age have unique barriers to becoming more active, such as multiple caring responsibilities and onset of chronic conditions, yet very few evidence-based, low-cost, scalable approaches to physical activity aim to reach a large proportion of them. Commencement of appropriate physical activity by women in their 50s should, therefore be a priority. We have designed an intervention to enhance physical activity participation in women aged 50+, which has been pilot-tested in a small sample and showed acceptability, uptake and positive recommendation. However, the promising impact observed on physical activity warrants further testing in a large trial.

3 STUDY OBJECTIVES

3.1 Primary Objective

The primary objective is to test the effectiveness of the Active Women over 50 program on average daily steps at 6 months compared with a waitlist control among women aged 50+.

3.2 Secondary Objectives

Secondary aims are (1) to evaluate the effectiveness of the Active Women over 50 program on physical activity, falls, mental wellbeing, physical function, quality of life, sleep, bodily pain, menopause symptoms, balance, fear of falling, action planning, and coping planning at 6 months after randomisation; (2) to evaluate the effectiveness of the Active Women over 50 program on goal attainment at 6 months after randomisation; (3) to evaluate the proportion of participants who i) achieve light physical activity and lower limit MVPA/week, ii) increase their daily steps by 2000+ from baseline to 6 months after randomisation; (4) to explore the experiences of participants of the Active Women over 50 program and to investigate contextual factors that affect the program uptake and maintenance; (5) to assess the cost-effectiveness, implementation potential and determinants to guide scale-up from the perspective of the healthcare and community funder; (6) to test secondary implementation outcomes (reach, fidelity and adoption, dose, sustainability); (7) To evaluate the number of daily steps for intervention participants 6 months after the program has ended, at 12 months after randomisation; (8) to evaluate the effect of the Active Women over 50 program on physical activity, falls, mental wellbeing, physical function, quality of life, sleep, bodily pain, menopause symptoms, balance, fear of falling, action planning, and coping planning for intervention participants 6 months after the program has ended, at 12 months after randomisation; (9) to evaluate the proportion of intervention participants who i) achieve light physical activity and lower limit MVPA/week, ii) increase their daily steps by 2000+ from 6 to 12 months after randomisation.

4 STUDY DESIGN

4.1 Type of Study and Participants

This study will use a two-arm parallel pragmatic hybrid type I effectiveness-implementation randomised controlled trial (n=1000) to test the effectiveness of the Active Women over 50 program on daily steps at 6 months compared with wait-list control among women aged 50+. In addition, a process evaluation will be undertaken to explore the experiences of participants in the intervention group after completing the program through interviews of approximately 30 participants and the impressions survey completed by all intervention group participants at 6-month follow-up. An economic analysis will also be carried out to evaluate cost-effectiveness, considering the perspective of both healthcare providers and community funders. The impact of the Active Women over 50 program on physical activity and secondary outcomes, 6 months after the program has ended, will be evaluated for intervention group participants 12 months after randomisation.

Participants will be randomly allocated in equal numbers to:

a) Immediate participation in the 6-month Active Women over 50 program (intervention group), n=500 or

b) Delayed participation in the Active Women over 50 program, waitlist control (control group, n=500)

4.2 Expected Duration of Study

The study is expected to take four years. We aim to recruit all 1000 participants within the first 3 years of the study. This will allow time to complete the 6-month, and optional 12-month, follow-up and data analysis within 15 months. Participant follow-up, data analysis and report writing will be completed within the 4-year grant timeframe, as outlined in Table 1.

Table 1: Trial timeline (n=1000) and recruitment plan

Task	Year 1	Year 2	Year 3	Year 4
Ethical approval, recruit staff, finalise intervention sites and procedures	✓			
Participants recruited in total (approx. 20/ week)	50	520	430	
Participants completed 6-month follow-up in total		400	400	200
Intervention group participants (n=500) completed optional 12-month follow-up in total		100	200	200
Data entry/ checking	✓	✓	✓	✓
Data analysis and manuscript draft completed.				✓

5. PARTICIPANT ENROLMENT AND RANDOMISATION

5.1 Recruitment

Advertising will be for the trial duration until 1000 participants have been recruited. We will advertise via the recruitment flyers and recruitment website. The recruitment flyer will provide the URL and a QR link to the recruitment website. The recruitment website will include the Participant Information Statement information. Advertising for trial participants will be undertaken through the general community via social media advertising and through community organisations, such as Arthritis NSW, the Council on the Ageing (COTA) NSW, and the Country Women's Association (CWA) of NSW and health promotion services that target women such as menopause services and BreastScreen NSW.
The recruitment flyers and website details will be distributed in newsletters, websites and social media (Facebook, LinkedIn and X (formerly known as Twitter)). The community organisations and promotion services will share the recruitment website and flyers on their social media accounts, website or in their newsletters. The recruitment website will have a link that will take potential participants to an online screening survey that will be hosted on REDCap on the University of Sydney server. The online screening survey will include the most up to date ethics approved Participant information Statement.

Advertising for trial participants will also be undertaken through online registries for research volunteers that enables volunteers to register their interest in taking part in ageing related research by a self-registration service. Registries will include *StepUp for Ageing Research* (https://www.stepupforageingresearch.org.au/) and *JoinUs* register (https://www.joinus.org.au/). Registries will be provided ethics-approved study documentation such as the ethics approval letter, trial protocol, participant information sheet, advertising flyers that contain the URL and a QR link to the Active Women over 50 study recruitment website. Registries will be requested to advertise the trial according to their privacy policy and will include but are not limited to StepUp for Research. StepUp for Research is an online self-registration service that enables volunteers to register their interest in taking part in dementia and/or ageing related research, either via StepUp for Dementia Research or StepUp for Ageing Research, respectively. The study team will only access the StepUp for Ageing Research component, and not the StepUp for Dementia Research component. The purpose of StepUp for Research is to allow such volunteers to be identified by researchers as potentially eligible for their studies. Researchers can then contact volunteers, in line with the volunteers' preferred method of contact, to discuss potential recruitment into a study. StepUp for Dementia Research was initially funded by the Commonwealth Department of Health and is delivered by the University of Sydney. StepUp for Research is not a research project but has been approved by the Human Research

Ethics Committee of the University of Sydney (project number 2018/680). The online service and all associated documentation, including methods of contacting volunteers and handling of data, were reviewed by a specially convened Governance Steering group within the University of Sydney which included experts in research ethics, data protection and information governance.

People who wish to participate will provide their contact details and consent for a member of the research team to telephone them to discuss their eligibility to participate. Prior assessing for eligibility, the research team will explain that the participant may require disclosing some personal information. Participants will be asked to provide verbal consent before they are asked some questions to confirm eligibility.

5.2 Eligibility Criteria

5.2.1 Inclusion Criteria

The trial will involve consenting adults who:

- Identify as a woman
- are aged 50 years and over
- live in the community across NSW
- do not meet the moderate-vigorous physical activity (MVPA) guidelines
- have access to an internet connected device
- want to receive support to be more active

5.2.2 Exclusion Criteria

The trial will exclude adults who:

- have insufficient English language skills to fully participate in the program
- have a medical condition that precludes participation in regular physical activity
- have a cognitive impairment (a diagnosis of dementia or a Memory Impairment Screen score of less than 5)
- have a progressive neurological disease (e.g., Parkinson‘s disease)
- are unable to leave the house independently and walk 10 metres unassisted.

5.3 Study sites

The trial will be conducted across urban, rural, regional, and remote areas of NSW.

5.4 Informed Consent Process

Potential participants will be provided with a participant information statement outlining the study procedures. The participant will have time to read the participant information sheet and discuss the study with family, friends and their local doctor if they choose to. Researchers at the University of Sydney will obtain online or written consent prior to any study commencement. After follow-up measures have been completed by the intervention group participants 6 months after randomisation, they will be provided with a second participant information statement. The statement will outline study procedures for participating in the follow-up study for an additional 6-months (ie., 12 months after randomisation). The participant will have time to read the participant information sheet and discuss their further involvement with family, friends and their local doctor if they choose to. Researchers at the University of Sydney will obtain online or written consent prior to any additional study participation. Participants will be made aware that the decision to participate will in no way influence any future decisions around their health care or any relationships with any organisations they have.

5.5 Enrolment and Randomisation Procedures

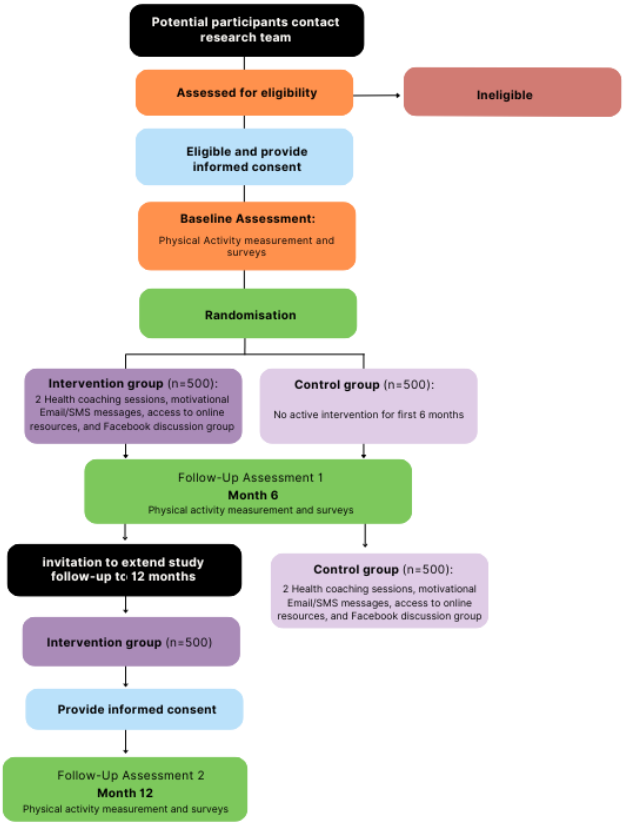
Participants will be enrolled into the study after initial screening to determine their suitability has been completed over the telephone, and having provided informed consent and completed all baseline surveys and device-based measurement of physical activity. Each participant will receive a study enrolment number, and this will be documented on all study documents. Group allocation will be determined using REDCap (Research Electronic Data Capture), a centralised web-based randomisation system within The University of Sydney with randomly permuted block sizes of four stratified by rural and urban locations. This will ensure concealment of allocation to groups and an auditable process.

5.6 Blinding Arrangements

The primary outcome will be collected in a blinded fashion. Accelerometer device data will be processed and analysed by staff unaware of group allocation. All baseline measurements will be undertaken prior to group allocation. Due to the nature of the intervention being tested, full blinding of participants to intervention group allocation will not be possible. All reassessment survey collection will be undertaken by researchers blinded to group allocation. The additional 12-month follow-up measures (accelerometer device and survey) for the intervention group participants will not be undertaken by researchers blinded to group allocation.

6 STUDY PROCEDURES SCHEDULE

Figure 1: Trial design



6.1 Intervention

The intervention group will receive access to the Active Women over 50 program. The Active Women over 50 program is a digitally delivered program designed with input from end-users across urban, regional and rural geographical settings and consists of four parts: 1) health coaching, 2) email or SMS behaviour change messages, 3) Active Women over 50 website, and 4) access to the Active Women over 50 private Facebook group.

6.1.2 Health coaching

Participants will receive two health coaching sessions, lasting up to 60 minutes, delivered by telephone or videoconference as preferred by the participant. The health coach will be a tertiary-qualified physiotherapist or other health professional trained and experienced in delivering empowerment-focused coaching to facilitate physical activity behaviour change. The first coaching session will take place within 2 weeks of randomisation, and the second session four weeks after the first. This person-

centred health coaching approach will provide information and education. The sessions will also draw on evidence-based behaviour change techniques, practice and theories to help participants set goals, action plan, and provide accountability through prompting, monitoring and reinforcement. The coach's role is to work with participants to make achievable choices, reinforce and evaluate progress, and facilitate accountability.

6.1.3 Email or SMS Behaviour Change Messages

Participants will choose the type of message platform and the frequency at which they would like to receive motivational messages over the 6-month period. Participants will choose between receiving unidirectional email messages that are delivered either weekly (24 emails), fortnightly (12 emails) or monthly (6 emails) frequencies over the 6-month period; or receiving SMS messages that are delivered once per week (24 SMS messages), twice per week (48 SMS messages), or three times per week (72 SMS messages) over the 6-month period. The emails and SMS messages will include several behaviour change techniques (BCTs). Both the email and SMS messages will deliver similar content informed by behaviour change theories. Secure marketing websites will be used to send the email messages and SMS messages.

6.1.4 Active Women over 50 Website

The website will emphasise the importance of becoming active from middle age for maintenance of health and physical function and prevention of falls in older age. Content will include three main pages (see Figure 2 below): "Why be active?", "How to be active", and "Be inspired". The "Why be active?" page includes evidence-based information about the effect of physical activity in middle-age to maintain health, longevity, and prevent disability in older age. The "How to be active" page includes practical suggestions for becoming more active using behaviour change techniques such as SMART goal setting, self-assessment of barriers to physical activity and solution-generation and included links to resources supporting habit formation and behaviour change, and information for different health conditions and services. The "Be inspired" page includes role modelling content to inspire participant's motivation to be physically active through video case studies and photo stories of "real life" women over 50, external podcasts, and blog posts. Participants will have the ability to access the website at their own discretion. Examples will reflect diversity of participant characteristics and place of residence (i.e., urban, regional, rural, remote).

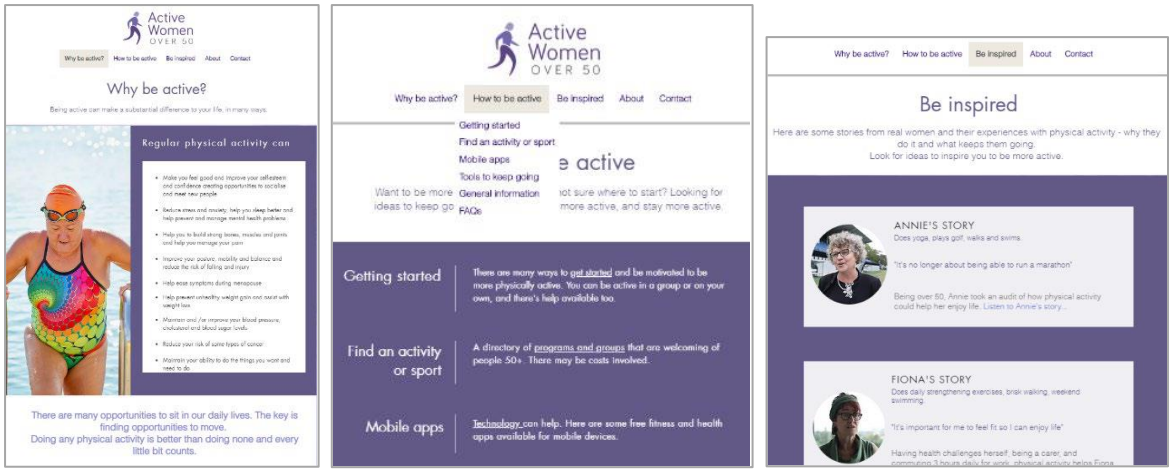


Figure 2. Screenshots of the Active Women over 50 website

6.1.5 Active Women over 50 private Facebook group

Participants will have access to a private Facebook group to support networking and social support (see Figure 3 below). Participants will be able to post comments to a common page (i.e., the group wall); view and respond to others' posts; create and post to discussion boards; and post web links, photographs, and videos. The private Facebook group will be moderated daily (Monday to Friday) by a member of the research team to ensure interactions are appropriate and relevant. Participants will be informed of the group rules, which will be both posted in the group, and pinned to the top of the group webpage. Only participants receiving the intervention will be granted access to the private Facebook group.

Figure 3. Screenshot of the Active Women over 50 private Facebook group page

6.2 Primary and Secondary Outcome Measures

Primary outcome: The average number of daily steps at 6 months after randomisation, measured objectively with an ActiGraph accelerometer.

Secondary outcomes: The secondary outcomes will be: Self-reported and device-measured physical activity, self-reported falls, mental wellbeing, physical function, quality of life, bodily pain, menopause symptoms, sleep, balance, fear of falling, action planning and coping planning at baseline, proportion achieving device-measured light physical activity and lower limit MVPA/week, and proportion who increased their daily steps by 2000+, measured with an ActiGraph activity monitor at 6 months after randomisation, and individualised goal attainment at 6 months after randomisation.

Additional secondary outcomes for the intervention group participants at 12 months after randomisation will be: self-reported falls, mental wellbeing, physical function, quality of life, bodily pain, menopause symptoms, sleep, balance, fear of falling, action planning and coping planning, proportion achieving device-measured light physical activity and lower limit MVPA/week, and proportion who increased their daily steps by 2000+, measured with an ActiGraph activity monitor at 12 months after randomisation, the average number of daily steps at 12 months after randomisation, measured with an ActiGraph activity monitor.

6.2.1 Assessment of primary outcomes

Physical activity will be assessed at baseline, and 6 months after randomisation over a seven-day period using a matchbox-sized accelerometer (ActiGraph GT3X+) worn on a belt at the hip or wrist. The device accurately estimates how physically active a person has been throughout the day by measuring 3D body accelerations. The data will be collected over a 7 day period to account for day-to-day variation in physical activity levels as per protocol from a previous trial.[20] The accelerometers will be posted to participants with clear instructions for use and telephone support will be available. Participants will be provided with pre-paid envelope to return the device to the research centre.

6.2.2 Assessment of secondary outcomes

The secondary outcomes will be assessed at baseline, and six months post-randomisation using self-report surveys and an accelerometer (ActiGraph GT3X+) (See Table 2) and will take approximately 20 minutes to complete. Additional secondary outcomes for the intervention group participants will be assessed twelve months post-randomisation in a similar manner with survey and accelerometer as described for the six-month follow-up. The Table 3 presents the schedule of assessments.

Table 2: Study secondary outcomes and measures

Secondary effectiveness outcomes	Measure
Self-reported physical activity	Single-item physical activity question *(In the past week, on how many days have you done a total of 30 minutes or more of physical activity, which was enough to raise your*

	breathing rate. This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places, but should not include housework or physical activity that may be part of your job") Frequency of participation in strength training and balance training
Falls rate	Monthly falls calendar
Mental wellbeing	Warwick-Edinburgh Mental Well-being Scale[21]
Physical function	PROMIS SF v2.0 – Physical Function 4a
Quality of life	EuroQol EQ-5D-5L[22]
Bodily pain	PROMIS SF v2.0 – Pain interference and Pain intensity 4a
Sleep	Pittsburgh Sleep Quality Index (PSQI)[23]
Balance	Perception of balance: *("Do you feel your balance is excellent, very good, good, fair, poor")*
Menopause symptoms	The Menopause-Specific Quality of Life Questionnaire
Fear of falling	*("Are you afraid of falling? (1 = not at all, 2 = little bit, 3 = moderately, 4 = quite a lot, 5 = extremely")*
Proportion achieving light physical activity and lower limit MVPA/week	Actigraph accelerometer
Proportion of people who increase their daily steps by 2000+ from baseline to 6 and baseline to 12 months after randomisation	Actigraph accelerometer
The average number of daily steps at 12 months after randomisation	ActiGraph accelerometer
Action Planning and Coping Planning	Action Planning and Coping Planning questionnaire[24]
Individualised goal attainment	Goal Attainment Scale at 6 months after randomisation

Table 3 Schedule of assessments

TIME POINT	$-t_1$	0	t_1	t_2	t_3	Monthly
ENROLMENT:						
Eligibility screen	✓					
Informed consent	✓					
Baseline surveys, Device measured activity Actigraph	✓					
Randomisation / Allocation		✓				
INTERVENTIONS:						
Active Women over 50 program		✓				
Waiting list control				✓		
OUTCOMES						
Number of falls measured with *monthly calendars for 6 months*						✓
Device-measured outcomes using Actigraph	✓		✓		✓	
Individualised goal attainment	✓		✓			
Self-reported secondary outcome measures	✓		✓		✓	

$-t_1$: baseline, prior randomisation; 0: after randomisation, t_1: 6-month follow-up; t_2: after 6-month follow-up completed; t_3: 12-month follow-up for intervention group participants

6.3 Cost-effectiveness outcomes

The cost of delivering the intervention and total costs of health and community service utilisation will be calculated for the cost-effectiveness analysis. Intervention costs will be estimated based on trial records where the resources required to implement the intervention will be recorded (e.g. staff time, any additional non-staff resources) and costed using appropriate wage rates and other relevant cost data. Healthcare and community-service utilisation will be collected over the trial period (6 months) on a monthly basis and costed using standard cost data such as IHPA, NHCDC and Medicare unit costs.

The main effectiveness outcomes of the economic evaluation will be physical activity (average steps per day measured with an ActiGraph), falls, physical function, and utility-based quality of life six months after baseline.

Utility-based quality of life will be measured using the EQ5D-5L and the health utility score, which is expressed as an index value for health, will be calculated from the 5 questions using published Australian scoring algorithms.[25] The scores fall on the 0.0 (dead) to 1.0 (perfect health) value scale.

Quality-adjusted life years (QALYs) will be calculated using the health utility score at baseline and 6-month follow-up. The number of QALYs gained or lost over the 6 months of follow-up will be calculated by multiplying the time spent in the health state by the relevant health utility score.

6.4 Process evaluation and implementation

The process evaluation is embedded in this study. Quantitative and qualitative methods will be used to assess the degree of successful program implementation (including reach the resources and intervention components used, type of message platform used/accessed), and the potential areas for improvement in relation to the intervention and its implementation. Implementation and scale-up considerations are described in Table 4.

In terms of acceptability, barriers and facilitators, participants' experiences of the intervention will be explored via post-intervention 'Impressions' surveys (sent to all intervention group participants once they complete the program) and semi-structured interviews with up to 30 purposively sampled participants, selected for maximum variation in age, geographical location, socio-economic status, carer responsibilities and engagement with the intervention (as reported in their Impressions survey). Questions in the survey and interviews cover attractions and expectations of the intervention, views of the intervention and its four components, any impacts, accounts of continuing/discontinuing participation, and questions related to the underlying program theory phrased in lay language. Survey and interview questions will be tested with consumer representatives and amended as required in line with their feedback prior to use in the trial. Qualitative data from free text comments in the surveys, and from transcriptions of the semi-structured interviews, will be analysed thematically. A workshop will be held with those involved in implementing the intervention to collate experiential views about what worked well and areas for improvement. The relationship between insights gained from qualitative analysis and trial outcomes will be explored.

If the intervention is effective, this process evaluation information will be used to guide future intervention design, for implementation at scale, including approaches for different participant profiles and contexts.

Table 4: Implementation outcomes

Outcomes	Definition as per McKay et al 2019[26]	Measurement tool
Reach	Proportion of the intended priority audience (i.e., participants) who participate in the intervention	Screening survey from recruitment website; baseline data form.
Adoption	Proportion and representativeness of providers or the delivery team that deliver an intervention	Study specific document maintained by trial manager; screening survey from recruitment website.
Fidelity	The extent to which an intervention is implemented as it was prescribed in the intervention protocol - by the delivery team	Study specific records
Dose (delivered)	Intended units of each intervention component delivered to participants by the delivery team	Study specific records
Determinants		
Acceptability (delivery team)	Perceptions among the delivery team that a given intervention is agreeable, palatable, or satisfactory	Qualitative interviews/ focus groups with delivery team
Acceptability (participants)	Perceptions among the participants that a given intervention is agreeable, palatable, or satisfactory	Includes 1. Study-specific documents on intervention components (e.g., agreement and participation in health coaching sessions); 2. data from message services on number who unsubscribe from messages, number messages opened; 3. Google analytics on website usage; 4. Engagement on Facebook; 5. Quantitative survey rating different elements of intervention; 6.

		Qualitative interviews with sub-group participants.
Cost	Money spent on design, adaptation, and implementation of an intervention	Study-specific log recording costs
Feasibility	Perceptions among the delivery team that an intervention can be successfully used or carried out within a given organisation or setting	Qualitative interviews/ focus groups with delivery team
Context	Aspects of the larger social, political, and economic environment that may influence intervention implementation	Field notes kept by Research Manager based on Consolidated Framework for Implementation Research (CFIR)
Adaptability	Extent to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs	Study-specific document guided by expanded Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME) framework (Wiltsey Stirman et al Imp Sci 2019)
Compatibility (appropriateness)	Extent to which an intervention fits with the mission, priorities, and values of organisations or settings	Stakeholders focus groups
Culture	Organisations' norms, values, and basic assumptions around selected health outcomes	Stakeholders focus groups
Complexity	Perceptions among the delivery team that a given intervention is relatively difficult to understand and use; number of different intervention components	Qualitative interviews/ focus groups with delivery team
Self-efficacy	Delivery team's belief in its ability to execute courses of action to achieve implementation goals	N/A
Potential for Scale-up	The scalability (the ability of a health intervention shown to be efficacious on a small scale and/or under	Intervention Scalability Assessment Tool (ISAT)[27]

	controlled conditions to be expanded under real world conditions to reach a greater proportion of the eligible population while retaining effectiveness [Milat et al 2013]) of a discrete health program or intervention	

6.5 Participant Withdrawal

6.5.1 Reasons for withdrawal

Possible reasons for participants to withdraw from the study may include illness, death, competing priorities, or simply no longer wishing to participate.

6.5.2 Handling of withdrawals and losses to follow-up

The Participant Information Sheet (PIS) and consent form will clearly state that participants are free to withdraw from the study at any time without affecting their future relationships with the researchers or organisations involved with this study. If participants decide to withdraw from the study, we will not collect any further information from them. Any information that we have already collected, however, will be kept and may be included in the study results. Participants will be assured that their decision will not have any impact on current or future relationship with the researchers at the University of Sydney or any other organisations associated with this study. To ensure a complete data set as possible, the study team will make every reasonable effort to contact and complete follow-up outcomes of every enrolled participant, including those who deviate from the intervention protocol. Attempts will be made to ensure all outcomes will be collected. At a minimum and only as a last resort, we will attempt to collect the primary outcome. Where possible, we will record the reason for loss to follow-up (e.g. consent withdrawn).

6.5.3 Replacements

Replacements for withdrawn participants will not be made. The sample size calculation assumed a dropout rate of 20%, which is higher than the expected drop-out rate, so we are confident that replacement of withdrawn participants will not be necessary to maintain study power.

6.6 Trial Closure

Participants will be followed up for 6 months after randomisation. Intervention group participants who consent to the additional follow-up measurement will be followed up for 12 months after

randomisation. Adverse events such as exercise related falls, musculoskeletal injury or cardiovascular events will be monitored by questions in the monthly health diaries..

7. STATISTICAL METHODS

7.1 Sample Size

A sample size of 1000 people (500/group) will provide 90% power to detect a between-group difference of 1000 steps/day (SD 4200), assuming 25% dropouts, alpha 5%. The sample size calculation was undertaken using the sampsi command in Stata.

7.2 Statistical Analysis

Analyses will be guided by a rigorous statistical analysis plan developed a priori as we have done previously and use an intention-to-treat approach. The primary outcome will be analysed using generalised linear regression to assess the effect of group allocation, with its corresponding baseline score as a covariate. Continuous secondary outcomes will be analysed using linear regression adjusting for the corresponding baseline measure of the outcome variable as appropriate. We will use log-binomial regression to determine the between-group difference in the proportion of people increasing daily steps by 2000+. Fall rates will be analysed using negative binomial regression models to estimate the difference in rates between groups after 6 and 12 months with exploratory analyses adjusting for amount of physical activity. There will also be pre-defined subgroup analyses included by age, rurality/remoteness of residence, number of medical conditions and baseline fall history. Analyses will be conducted using Stata 14 software.

7.3 Economic evaluation

Economic evaluation will take a health and community care funder perspective and will aim to establish the cost-effectiveness and cost-utility of the Active Women over 50 intervention compared to waitlist control. We will calculate intervention delivery costs and community services and health service utilisation costs during the trial period for both groups. Using mean costs and mean health outcomes in each trial arm, the incremental cost per 1) additional person increasing physical activity by 2000+ steps/day, 2) additional fall prevented, 3) additional person achieving a meaningful improvement in physical function, and 4) quality-adjusted life years (QALY) gained of the intervention group compared with control group, will be calculated. Bootstrapping will estimate a distribution around costs and health outcomes and will be used to calculate the confidence intervals around the

incremental cost-effectiveness ratios. The results will be plotted on the cost-effectiveness plane, and as cost-effectiveness acceptability curves.

A range of additional sensitivity analyses will be conducted to determine the impact on the ICER of various assumptions within the economic evaluation, such as different costing methods and strategies for handling missing data.

8 ADVERSE EVENT REPORTING

8.1 Definitions

Adverse events (AEs) are defined as incidents in which harm resulted to a person receiving health care" (AIWH http://www.aihw.gov.au/haag11-12/adverse-events/; accessed 2015.02.19). For the purpose of the Active Women over 50 trial, an AE is defined as an unwanted and usually harmful outcome (e.g. fall, seizure, cardiac event). The event may or may not be related to the intervention, but it occurs while the person is participating in the intervention i.e. while they are doing physical activity. Adverse events will be categorized as minor AEs (MAEs) or serious AEs (SAEs). A MAE is defined as an incident that occurs while the person is participating in the intervention that results in no injury or minor injury. For example, a fall where the person sustains a small cut or bruise that requires none or minor medical intervention. A SAE is defined as an incident that occurs while the person is participating in the intervention that results in death, serious injury or re-hospitalisation. Examples of SAEs are:

- Death
- Myocardial infarction
- Serious falls
- Serious fractures

8.2 Assessment and Documentation of Adverse Events

The Research Manager will be notified within 12 hours of any research staff member witnessing or becoming aware of a participant reporting an AE (e.g. through monthly health diaries, phone calls, texts, emails, communication from someone known to the participant). The research staff member will complete an AE data form within 24 hours of knowing about the AE. If a SAE occurs, the Research Manager will notify the lead investigator within 48 hours.

8.3 Eliciting Adverse Event Information

Participants will be asked about the occurrence of Adverse Events (AE) in the monthly health diaries.

Minor AE or Serious AE; type of adverse event; setting for adverse event; date/time AE; involved furniture/equipment; specify other furniture/equipment; specify intervention technology; location of AE; inside or outside; Inside activity at time of AE; Inside place where AE occurred; outside activity at time of AE; specify other outside activity; outside place where AE occurred; specify other outside place where AE occurred; primary cause of AE; injuries sustained; specify fracture type; specify other type of injury; interventions to manage AE; specify other intervention to manage AE; AE witnessed (specify); using a walking aid at time of AE; how was the AE notified.

8.4 Serious Adverse Event Reporting

8.4.1 SAEs

Reporting of SAEs will follow The University of Sydney standard operating procedure on clinical trial safety reporting, using the SAE definition and procedures outlined above.

Data monitoring: We will establish an independent Data and Safety Monitoring Board (DSMB) to monitor adverse events and adherence to the trial protocol to ensure participant safety. The purpose and roles of the DSMB, as well as stopping rules due to safety concerns will be determined a priori.

Trial reporting will be guided by the CONSORT Statement and extensions as well as the TIDieR guide for intervention description, and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement. The trial will be run to ICH-GCP standards and registered with the ANZ Clinical Trials Registry prior to commencement. The protocol will be peer reviewed and published and will follow the SPIRIT guidelines.

9 DATA MANAGEMENT

9.1 Data Collection

Data will be collected by surveys completed online or in paper format and via Actigraph activity monitor posted to participants at baseline, and 6-month follow-up. Data will be collected by survey and Actigraph activity monitor at an additional timepoint of 12 months post-randomisation for intervention participants who consent to participating in the n additional 6 months of follow-up. Telephone interviews will be audio recorded to capture participants' views accurately. The audio files only will be stored on the University of Sydney password protected research data store and deleted from the local drive.

9.2 Data Storage

Data Collection forms will be stored at the following locations.

Site name: Institute for Musculoskeletal Health, School of Public Health

Location of stored data: KGV Building, Room 13/10/049, Level 10, Missenden Road, Camperdown NSW 2050.

Format of paper-based stored participant data: Participant data will be coded with a unique study ID number. Participant data will be collected electronically via the Redcap system. Any paper-based consent forms or surveys will be scanned and stored digitally, and paper-based copies securely destroyed.

Format of electronic data: All data will be entered onto a password protected REDCap database, with license held by The University of Sydney. The interviews will be conducted over the telephone by experienced qualitative researcher from the research team. Telephone interviews will be audio recorded to capture participants' views accurately. The audio files only will be stored on the University of Sydney password protected research data store and deleted from the local drive. Access to the data will be limited to authorised study staff and investigators. Study staff and investigators will have differing levels of access to the database by use of User roles which stipulates what data different types of study staff can view and download.

Duration data will be stored: All data will be stored for 15 years from the study completion in a secure manner at The University of Sydney.

Method of destruction of data: Paper files will be shredded; computer files will be securely deleted.

9.3 Data Confidentiality

To ensure confidentiality, the final dataset will contain re-identifiable information only. All publications associated with the results of the study will involve de-identified data so participant confidentiality will be maintained. Demographic information linking the participant to the data will be stored on a separate file. Only the lead investigator will have access to this information at the conclusion of the study.

9.4 Study Record Retention

All data will be stored and retained for 15 years from the study completion in a secure manner at The University of Sydney.

9.5 Data Sharing

Deidentified participant data underlying main results may be accessed by researchers who provide a methodological proposal directed to the Principal Investigator. Approval for data access will be granted on a case-by-case basis at the discretion of the Principal Investigator. The data will be accessible from the date of this article's publication and will be available for a period of 5 years.

10 ADMINISTRATIVE ASPECTS

The study protocol will be submitted for publication and will be registered on the Australian and New Zealand Clinical Trials Registry prior to enrolment of the first participant.

10.1 Independent HREC approval

Not applicable

10.2 Amendments to the protocol

It is agreed that any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

10.3 Protocol deviations

It is agreed that any protocol deviations will be submitted to the HREC for review.

10.4 Participant reimbursement

There is no participant reimbursement.

10.5 Financial disclosure and conflicts of interest

There are no existing conflicts of interest for this project.

11 USE OF DATA AND PUBLICATIONS POLICY

The results of the study will be published in a peer reviewed scientific journal and presented at relevant scientific conferences. Data will be de-identified prior to the quantitative analysis. A lay summary of the results will be made available to all participants at the completion of the study. A publication policy will be devised prior to study completion that outlines the lead author and co-authors for all intended publications.

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