

Choose to Move

IMPLEMENTATION OF THE CHOOSE TO MOVE PROGRAM IN SYDNEY AUSTRALIA

CONFIDENTIAL

STATEMENT OF COMPLIANCE FOR NON-DRUG / NON-DEVICE CLINICAL TRIALS

This document is a protocol for a clinical research study.

The clinical trial will be conducted in compliance with all stipulations of this protocol, the conditions of human research ethics committee approvals, the [NHMRC National Statement on Ethical Conduct in Human Research](#) (as updated) and the [Handbook for Good Clinical Research Practice \(GCP\)](#). The Therapeutic Goods Administration has adopted the [ICH Guideline for Good Clinical Practice](#).

PROTOCOL SIGNATURE PAGE

Protocol title: Implementation of the *Choose to Move* program in Sydney Australia

Protocol number: 3

Protocol version and date: Version 3.0, 02/09/2024

Sponsor name: The University of Sydney

Principal Investigator Declaration

I will conduct the clinical trial in accordance with Good Clinical Practice, Declaration of Helsinki, National Statement on Ethical Conduct in Human Research 2007 (as updated), Australian Code for the Responsible Conduct of Research 2018 and the moral, ethical and scientific principles that justify clinical research. The clinical trial will be conducted in accordance with all relevant laws and regulations relating to clinical studies and the protection of participants.

I agree to adhere to the protocol as approved by the Human Research Ethics Committee/s in all circumstances other than where necessary to protect the well-being of the participant.

(Coordinating) Principal Investigator name: Professor Anne Tiedemann

CONTENTS

Protocol signature page.....	2
Contents	3
1. General information	4
2. Synopsis	5
3. Rationale / Background	7
4. Aims / Objectives / Hypotheses.....	8
5. Participating sites	8
6. Research plan / study design	8
7. Ethical considerations.....	17
8. Safety considerations	19
9. Outcomes	19
10. Data management.....	23
11. Timelines / Milestones	24
12. Financial	24
13. Publication policy / Dissemination of results	25
14. References	25
15. Appendices	26

1. GENERAL INFORMATION

1.1 Protocol Title

Implementation of the *Choose to Move* program in Sydney Australia

1.2 Protocol identifying number

Version 3.0, 02/09/2024

1.3 Sponsor and funding

The University of Sydney will be the sponsor of this study.

The NHMRC-CIHR Healthy Cities Implementation Science Team Grant Scheme grant (APP 2018862) will be funding the study. This is under the project title “Choose to Move Sydney”.

1.4 Project team

Chief Investigator

- Professor Anne Tiedemann, Professor of Physical Activity and Health, Faculty of Medicine and Health, The University of Sydney

Investigators

- Professor Heather McKay, Professor of Active Aging Research Team, University of British Columbia
- Professor Catherine Sherrington, Senior Principal Research Fellow, Faculty of Medicine and Health, The University of Sydney
- Associate Professor Leanne Hassett, Principal Research Fellow, Faculty of Medicine and Health, The University of Sydney
- Professor Luke Wolfenden, NHMRC Principal Research Fellow, University of Newcastle
- Emeritus Professor Adrian Bauman, The University of Sydney
- Professor Philayrath Phongsavan, Professor of Public Health, Faculty of Medicine and Health, The University of Sydney
- Professor Benjamin Smith, Professor of Public Health, Faculty of Medicine and Health, The University of Sydney
- Dr Juliana S Oliveira, Early Career Researcher, Faculty of Medicine and Health, The University of Sydney
- Dr James Kite, Lecturer in the Prevention Research Collaboration, Faculty of Medicine and Health, The University of Sydney

Associate Investigators

- Adrian Prakash, General Manager of SHARE
- Dr Bernadette Brady, SPHERE Clinical Research Fellow, The University of Sydney
- Professor Dawn Mackay, Director of the Aging and Population, Simon Fraser University
- Associate Professor Joanie Sims Gould, The University of British Columbia

Research Team

- Ms Sandra O'Rourke, School of Public Health, Faculty of Medicine and Health, The University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
- Ms Catherine Kirkham, School of Public Health, Faculty of Medicine and Health, The University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
- Ms Elisabeth Ramsay, School of Public Health, Faculty of Medicine and Health, The University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
- Mr Daniel Cheung, School of Public Health, Faculty of Medicine and Health, The University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia
- Ms Courtney West, School of Public Health, Faculty of Medicine and Health, The University of Sydney, Institute for Musculoskeletal Health, Sydney, Australia

1.5 Collaborations

Our research team are collaborating in partnership with the Active Aging Research Team from the University of British Columbia who developed, implemented, and scaled up the *Choose to Move* program in Canada.

Our research team will engage with Sydney-based organisation SHARE (not-for-profit organisation), who offer low-cost exercise programs to people aged 50+, as our delivery partner for this research. We will adapt the *Choose to Move* program to achieve the best fit for the local context. We will identify specific implementation strategies (e.g. training, recruitment) that align with the priorities and capacity of the delivery partner SHARE.

1.6 Trial Registration

The study will be registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) <http://www.anzctr.org.au> prior to commencement.

2. SYNOPSIS

TITLE	Implementation of the <i>Choose to Move</i> program in Sydney Australia
OBJECTIVES	This study has the following core objectives: <ol style="list-style-type: none"> 1. Describe adaptation of the <i>Choose to Move</i> program and implementation strategies to achieve “best fit” for older adults in Sydney. 2. Evaluate implementation of CTM programs, including use of implementation strategies. 3. Evaluate the acceptability and adherence of the <i>Choose to Move</i> program for older adults in Sydney. 4. Evaluate program effectiveness- measure if the <i>Choose to Move</i> program benefits health outcomes (e.g., physical activity, mobility, social isolation) in older adults in Sydney.
PRIMARY HYPOTHESIS	We hypothesise: <ol style="list-style-type: none"> 1. The <i>Choose to Move</i> program and implementation strategies will require minor adaptations to suit the needs of people aged 50 and over in Sydney. 2. The <i>Choose to Move</i> program will be implemented with fidelity. 3. The <i>Choose to Move</i> program will be acceptable and well attended by people aged 50 and over in Sydney. 4. The <i>Choose to Move</i> program will provide benefits to health outcomes to people aged 50 and over in Sydney.
DESIGN	This is an uncontrolled, single group implementation study that is focused on implementing the <i>Choose to Move</i> program in Sydney, Australia. This will be through a process of: <ol style="list-style-type: none"> 1. Adaptation: Co-design adaptation of the program and implementation strategies for adults in Sydney 2. Program implementation and delivery: build organisation capacity and support delivery partners on implementation, deliver 3-month intervention. 3. Evaluation: Describe and assess implementation strategies used to achieve ‘best fit’ and to measure <i>Choose to Move</i> program benefits for various health outcomes.
BLINDING / MASKING	Open (masking not used)

<p>OUTCOMES</p>	<p>Primary effectiveness outcome: Physical activity (PA) will be assessed using the single item measure of self-reported number of days engaging in at least 30 minutes of moderate physical activity per week.</p> <p>Secondary effectiveness outcomes: Self-reported single item questions about days per week doing muscle strengthening activities and balance training, ability to walk 400m and 1 flight of stairs, health limitations affecting activities, sedentary behaviour, quality of life, social isolation, loneliness, perception of balance, fear of falling, number of falls in past 12 months, adverse events at follow up and Short Physical Performance Battery.</p> <p>Implementation outcomes: Reach, adoption, fidelity, dose, sustainability.</p> <p>Implementation determinants: Acceptability, cost, feasibility, adaptability, compatibility, culture, complexity, self-efficacy</p> <p>Qualitative outcomes: Participant acceptability, barriers, facilitators, and participant experience.</p> <p>Cost outcomes: Study-specific logs will be used to record costs associated with design, adaptation and intervention delivery and could be used to create a decision analytic model to conduct a simulated cost-effectiveness analysis.</p>
<p>STUDY DURATION</p>	<p>We aim to recruit all participants between Oct 2024 and December 2026. Data analysis and report writing will be completed by December 2027.</p>
<p>INTERVENTION/S</p>	<p><i>Choose to Move</i> is a 3-month program that provides motivation and support for adults aged 50 years and over to become more physically active and socially connected. Participants work with a trained activity coach in groups to set health goals and develop a personalised physical activity plan.</p> <p>The program involves:</p> <ul style="list-style-type: none"> • One-one consultation action planning (30min). • Group meetings (8x1 hour sessions over 3 months): Activity coaches will deliver education on various health topics, share community resources and facilitate group discussions. • Access to the Choose to Move website. • Access to the Choose to Move Facebook group. • Resources - group meeting PowerPoint presentations, handouts and fortnightly newsletters).
<p>NUMBER OF PARTICIPANTS</p>	<p>16 programs with average of 10 participants per program will provide a total of 160 participants.</p>
<p>POPULATION</p>	<p>160 adults aged 50+ living in the community (Sydney, Australia) and who are not currently meeting physical activity guidelines and would like support to be more physically active.</p>
<p>SELECTION AND ENROLMENT</p>	<p>Inclusion Criteria</p> <p>The study will involve consenting adults who:</p> <ol style="list-style-type: none"> 1. aged over 50. 2. consider themselves inactive (do less than 150 minutes of moderate physical activity per week).

	<ol style="list-style-type: none"> 3. want to receive physical support to be more active. 4. able to commit to a 3-month program. 5. live in the community across Sydney. <p>Exclusion Criteria</p> <p>The study will exclude adults who:</p> <ol style="list-style-type: none"> 1. have insufficient English language skills to fully participate in the program. 2. have a medical condition that precludes participation in regular physical activity. 3. have a diagnosed cognitive impairment. 4. have a progressive neurological disease (e.g., Parkinson's disease). 5. are unable to leave the house independently and walk 10 metres unassisted.
--	--

3. RATIONALE / BACKGROUND

The World Health Organization (WHO) estimates that between 2015 and 2050, the proportion of the world's population over 60 years of age will nearly double from 12% to 22%. The pace of population ageing is increasing, and "all countries face major challenges to ensure that their health and social systems are ready to make the most of this demographic shift"¹. Australia's population, along with the global population, is ageing. In 2020 there were more than 4 million people in Australia who were aged 65 and over. The proportion of people aged 65 and older is expected to grow by 31% by 2030 and by 55% by 2040².

The physical activity guidelines for people aged 65+ recommend that they engage in at least 30 minutes of moderate intensity physical activity on most, preferably all, days. Despite the many benefits of physical activity, only 41.8% of older Australians are meeting these guidelines³. Physical activity participation has enormous untapped potential as a cost-effective approach to enhancing health in people of most ages, health conditions and physical abilities⁴. A Lancet editorial⁴ calls for physical activity to be taken more seriously as a population health intervention, given the strong evidence of physical and mental health benefits yet poor participation rates. As well as prevention and management of chronic conditions, physical activity is now known to have survival benefits⁵.

Choose to Move (CTM) is a community-based program, co-designed with older adults, that increases physical activity and mobility and reduces social isolation⁶. *Choose to Move* integrates behaviour change principles into two components:

1. One-to-one consultation action plan meeting
2. Motivational activity coach-led group sessions

The *Choose to Move* program was successfully developed and implemented in Canada by the Active Aging Research Team at the University of British Columbia, with funding from the Government of British Columbia. *Choose to Move* was rigorously developed with implementation science principles. It is scalable, co-designed, adaptable, tailored for communities, and based on authentic partnerships.

Social connectedness and loneliness are important aspects of the *Choose to Move* program. Social connectedness is defined as 'feelings of interpersonal connection and meaningful, close, and constructive relationships with others (individuals, groups, and society)⁶. A socially connected person feels that they; care about others and are cared about by others and belong to a group or community. Caring and respect in social relationships prompts a sense of well-being together they act as a buffer against health problems and catalyse myriad health benefits⁷. Loneliness is a perceived lack in quality or quantity of one's relationships⁸ and is closely linked with accelerated loss of physical functioning and health with age, and an increased likelihood that an older person discontinues PA over time^{9,10}.

Researchers are now advocating for interventions that aim to enhance social connectedness and reduce loneliness in older people¹¹.

Choose to Move program has not been implemented in Australia, so this research will generate new knowledge of how this intervention can be scaled up to promote health in adults aged 50 and over. This research will bring enormous benefit to Australia in terms of new knowledge, researcher capacity building and international collaboration for knowledge exchange. We will target people in Sydney, who are currently insufficiently active and who would like support to be more active. The World Health Organisation 2018 Global Action Plan on Physical Activity set a global target of 15% improvement in physical activity by 2030. Our research will help Australia reach this target and align with the World Health Organisation's call for research investment in strategies that support people to maintain physical activity capacity in their older age.

4. AIMS / OBJECTIVES / HYPOTHESES

This research study main objectives will be to adapt and implement the *Choose to Move* program to the Australian context. The study core objectives are as follows:

This study has the following core objectives:

1. Describe adaptation of the *Choose to Move* program and implementation strategies to achieve "best fit" for older adults in Sydney.
2. Evaluate implementation of CTM programs, including use of implementation strategies.
3. Evaluate the acceptability and adherence of the *Choose to Move* program for older adults in Sydney.
4. Evaluate program effectiveness- measure if the *Choose to Move* program benefits health outcomes (e.g., physical activity, mobility, social isolation) in older adults in Sydney.

We hypothesise:

1. The *Choose to Move* program and implementation strategies will require minor adaptations to suit the needs of people aged 50 and over in Sydney.
2. The *Choose to Move* program will be implemented with fidelity.
3. The *Choose to Move* program will be acceptable and well attended by people aged 50 and over in Sydney.
4. The *Choose to Move* program will provide benefits to health outcomes to people aged 50 and over in Sydney.

5. PARTICIPATING SITES

The study will be conducted across metropolitan areas of Sydney where our delivery partner organisation SHARE is based. In addition, occasional online classes (via zoom) may be made available if there is a demand for those who cannot access a community organisation site.

Current delivery partner organisations include:

- SHARE (non-for-profit organisation) who has multiple sites across metropolitan areas of Sydney.

6. RESEARCH PLAN / STUDY DESIGN

6.1 Type of study

This is an uncontrolled, single group implementation study that is focused on implementing the *Choose to Move* program across Sydney, Australia. This will be through a process of:

1. Adaptation: Co-design implementation strategies to adapt the program for adults in Sydney.
2. Intervention: Deliver 3-month intervention, build organisation capacity and support delivery partners on implementation
3. Evaluation: Measure the acceptability and adherence of the CTM program
4. Evaluation: Describe and assess implementation strategies used to achieve 'best fit' and to measure CTM program benefits for various health outcomes.

6.2 Population / Sample size including power calculation.

16 programs with an average of 10 participants per program will provide a total of 160 participants to detect a difference in the proportion of participants who increase their physical activity level from baseline to 3-months (approximately 1 day/week), allowing for 20% dropout.

Sample Size: To attain >80% power to detect an increase in PA of approximately 1 day/wk as per CTM Phase 3 (PA by the single-item measure; T1 = 2.5 d/wk.; T2 = 3.4 d/wk.; SD difference = 2.2) with alpha of 0.05 across two comparisons (T2 vs.T1), an intraclass correlation for PA of 0.05 (to account for the clustered design of participants within programs) and estimated 20% drop out.

6.3 Study duration

The study is expected to take four years. We aim to recruit all 160 participants within the first 2.5 years of the study. This will allow time to complete the follow-up and data analysis. Participant follow-up, data analysis and report writing will be completed within the 4-year grant timeframe, as outlined in Table 1.

Table 1: Study timeline (n= 160) 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	20	70	70	00
Participants completed 3- and 9-month follow-up in total	20	70	70	70
Data entry/ checking	✓	✓	✓	✓
Data analysis and manuscript draft completed.				✓

6.4 Statistical analyses

Analyses will be guided by a rigorous statistical analysis plan developed a priori as we have done previously. Continuous primary and secondary outcomes will be analysed using linear regression. Dichotomous secondary outcomes will be analysed with chi-squared tests. Analyses will be conducted using Stata 14 software.

6.5 Recruitment and selection of participants, delivery partner organisations and activity coaches

Participants

Advertising for participants will be undertaken through the general community via social media advertising and through our partner community organisation. We will advertise using our recruitment flyers in newsletters, websites, and social media [Facebook, LinkedIn, and X (formerly known as Twitter)]. The delivery partner organisation will use our recruitment flyer on their social media accounts, websites and in their newsletters. The advertising across social media will occur on an as needed basis. Paid advertisements will run for 5-7 days at a time. The paid advertisements will target different areas of Sydney (e.g., advertisement may target a specific area where a partner organisation resides and will run the program from) thereby not spamming the same people with every advertisement.

The recruitment flyer will have a link or QR code that will take potential participants to a screening survey that will be hosted on REDCap on the University of Sydney server. Here participants will have access to the most up to date ethics approved Participant Information Statement. People who wish to participate or find out more information will provide their contact details and consent for a member of the research team to telephone them to discuss the program in more detail. Screening for eligibility will only be conducted by The University of Sydney research team. Prior to assessing for eligibility, the research team will explain that the participant may be required to disclose some personal information and participants will be asked to provide verbal consent to do so. People who do not meet the eligibility criteria, or choose not to participate, will have any identifiable information destroyed.

If participants are eligible, they will be invited to attend an information session 1-2 weeks before the program starts to provide more detail and help decide if *Choose to Move* is right for them. Consent to

participate in the *Choose to Move* program will be obtained by researchers at The University of Sydney not the partner organisations (SHARE). Consent will be obtained online or paper based written form.

Delivery partner organisation

Our research team will engage with Sydney-based organisation SHARE (not-for-profit organisation), who offer low-cost exercise programs to people aged 50+, as our delivery partner for this research. No recruitment will be necessary.

Activity Coaches

Activity coaches that will be used to deliver the *Choose to Move* program are already part of the University of Sydney research team or group fitness leaders' employees of SHARE. No recruitment will be necessary. No formal qualification is needed to be an activity coach on the *Choose to Move* study just experience with working with adults aged 50 and over.

6.5.1 Inclusion and exclusion criteria

Participants

The target population is adults aged 50 and over living in the community (in Sydney, Australia), who are insufficiently active and interested in receiving support to be more active.

Inclusion Criteria

The study will involve consenting adults who:

- Are aged 50 and over.
- Consider themselves inactive (do less than 150 minutes of moderate physical activity per week).
- Want to receive support to be more active.
- Are able to commit to a 3-month program.
- Live in the community across Sydney.

Exclusion Criteria

The study 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 diagnosed cognitive impairment.
- Have a progressive neurological disease (e.g., Parkinson's disease).
- Are unable to leave the house independently and walk 10 metres unassisted.
- Do not have access to internet if choose to do an online class.

6.5.2 Interventions

Choose to Move program

The program consists of the following components:

- **A one-on-one consultation** (30-minutes) with the activity coach. The consultation helps participants set health-related goals and develop a physical activity action plan that fits their routine and suits their interests, goals, abilities, and resources. The consultation session will be delivered face to face or by telephone or videoconference as preferred by the participant. The activity coach will have experience working with older adults and be aware of supports and services in their community to help facilitate physical activity behaviour change. The coaching session will take place in week two of the program. The session will also draw on evidence-based behaviour change techniques, practice, and theories to help participants set goals, action plan, and provide accountability. The activity coach will review the Tell Me About Yourself form and get active form as part of this session.
- **Group meetings (8 x 1-hour)** where participants connect with others in their group to share experiences, encourage and motivate each other. Participants learn about various health topics (e.g., falls prevention, stress management, nutrition) and resources available in their communities. Participants receive the most support during the first six weeks of the program. The first six weeks includes contact every week via a one-on-one consultation and 5 group meetings. This provides the individual and group support they need to set goals and to build

physical activity into their lives. In the final six weeks, participants attend three group meetings, during weeks 8, 10, and 12. These meetings help keep participants on-track and set longer-term goals as they approach the end of *Choose to Move*. The Tell Me About Yourself form will be completed during group session 1 and is used to inform the activity coach about the goal(s) the participant is interested in setting, activities they currently do or would like to do, any pain they may be experiencing, and their interest in being active with other people.

- **Access to the *Choose to Move* Website** the participants will have access to an existing *Choose to Move* website that contains a collection of trusted resources. Materials and information include links to exercise videos and printable resources on topics such as strength, balance, flexibility, bone and joint health. Participants will have the ability to access the resources at their own discretion.
- **Facebook page:** Participants will have access to the public *Choose to Move* Facebook page which will have resources and information on physical activity.
<https://www.facebook.com/ChooseToMovement>
- **Resources** – Group meeting PowerPoint presentations, handouts and fortnightly newsletters. Each group meeting will have a PowerPoint presentation focused on a specific health topic that the activity coaches will deliver. After each group meeting there is an accompanying handout. It includes a summary of key information specific to individual group meeting as well as links to additional resources. They will emphasise the importance of being active, maintaining of health and physical function. Participants also have the option of signing up for a fortnightly newsletter to receive updates about the program and receive additional resources to help keep active.

6.5.3 Randomisation and blinding processes

This is a non-randomised study. All participants will receive the *Choose to Move* program for 3 months, so masking is not required. Figure 1 shows the flow of participants through the *Choose to Move* program.

6.5.4 Schedule of events

The timing of the *Choose to Move* intervention components over the 12-week period is outlined in Table 2. The timing for measures collected for relevant stakeholders are outlined in Table 3.

Table 2: *Choose to Move* component delivery timeline.

Program Week		1	2	3	4	5	6	7	8	9	10	11	12
Information Session	●												
Motivational Group Meeting		●		●	●	●	●		●		●		●
One-on-One Consultation			●										

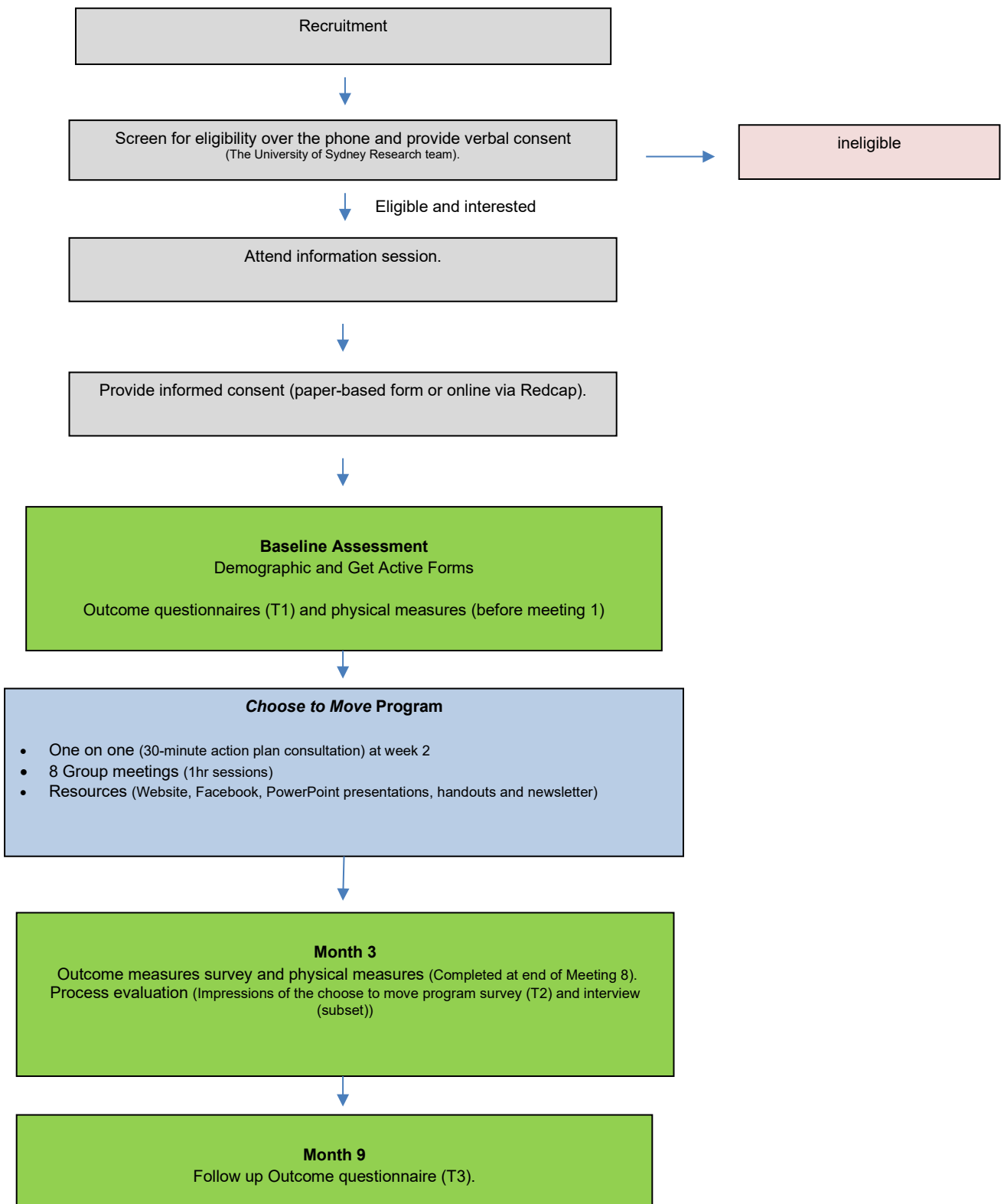
Note: the weeks may be slightly adjusted based on room availability at the delivery organisations venue and other unforeseen events such as public holidays.

Table 3: Overview of measures collected for each participant group and various time points.

Participant group	Measures	Planning (T0)	Baseline of Program (T1)	3 months (on completion of program) (T2)	9 months (6 months post program) (T3)
Participants	Demographic and Get Active Forms		Y		
	Outcome measures survey		Y	Y	Y
	Impressions of the choose to move program survey (end of program feedback)			Y	
	Interviews (subset) end of program			Y	
Activity Coach	Training Survey	Y			
	Feedback Survey			Y	
	Interview (subset) end of program			Y	
Organisations representatives (Director/manager) (SHARE)	Feedback Survey end of program			Y*	
	Interview (Directors/manager) end of program			Y*	

*Follow up survey and interview by organisation representative will only be completed at the end of the last program delivery.

Figure 1. Flow of participants



Choose to Move and implementation strategies for Sydney

The research project team will engage with participants and partner organisation SHARE in an adaption process to adapt the *Choose to Move* program to achieve the best fit and identify specific implementation strategies (e.g. training, recruitment) that align with the priorities and capacity of the delivery partner SHARE that will implement the program.

What support do organisations receive?

The team at the University of Sydney will work with partner organisation SHARE to understand how *Choose to Move* might fit and complement their existing programs and activities (Table 4). SHARE will receive funding to cover delivery costs for staff.

Table 4: The support provided to organisations (implementation strategies).

Adaptation support	<p>...meet to identify any adaptations that might be needed for <i>Choose to Move</i> to meet the needs of SHARE community. Examples include:</p> <ul style="list-style-type: none"> ▪ Adjusting the program schedule ▪ Including volunteer support
Recruitment/ referral resources and planning support	<p>...support to recruit <i>Choose to Move</i> participants. Support can include:</p> <ul style="list-style-type: none"> ▪ Recruitment strategy brainstorming ▪ Promotional material templates (e.g., posters)
Activity coach training	<p>...train all activity coaches to deliver <i>Choose to Move</i>. Training takes place online (~7h to complete) and includes self-directed and interactive modules that cover:</p> <ul style="list-style-type: none"> ▪ <i>Choose to Move</i> program delivery details <ul style="list-style-type: none"> ▪ One-on-one consultations ▪ Group meetings ▪ Facilitation and group management skills Interactive problem solving regarding common program scenarios
Program materials	<p>...provide all materials needed to deliver <i>Choose to Move</i>, including:</p> <ul style="list-style-type: none"> ▪ Group meeting guides/slides ▪ Participant intake forms ▪ Administrative documents ▪ Attendance record ▪ Delivery checklist
Participant materials	<p>...provide participant materials, including:</p> <ul style="list-style-type: none"> ▪ Action plans ▪ Group meeting summaries/handouts ▪ Activity log
Ongoing support	<p>...be available to answer any questions throughout the duration of the delivery agreement. The support team will schedule regular check-in calls during the first program, then as needed.</p>

All program materials have been successfully developed and implemented by the Active Aging Research Team at the University of British Columbia. They have been adapted by our research team to suit the context in Sydney, Australia especially in areas such as community resource links and contact numbers.

6.5.5 Withdrawal / termination

Possible reasons for participants to withdraw from the study may include illness, death, competing priorities, or simply no longer wishing to participate. Participants will be made aware as clearly stated in the Participant Information Sheet (PIS) and consent form that they are free to withdraw from the study at any time. Their decision to withdraw from the study will in no way influence any current or future relationships they have with the University of Sydney or partner organisation SHARE.

The study team will make every reasonable effort to contact and complete follow-up of every participant, including those who deviate from the intervention protocol. Attempts will be made to ensure all outcomes will be collected. Where possible, we will record the reason for loss to follow-up and the date and reason for withdrawal on the password protected REDCap database, with license held by The University of Sydney.

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 Informed consent process

Participants

Potential participants will be provided with a participant information statement outlining the study procedures. The participants will have time to read the participant information sheet and discuss the study with family, friends and their local doctor and attend the *Choose to Move* information session before informed consent. Consent to participate in the *Choose to Move* program will be obtained by researchers at The University of Sydney not the partner organisations. Researchers will obtain online consent (via a Redcap Link) or written consent on a paper-based form prior to any program commencement for each participant. Participants will be made aware that the decision to participate will in no way influence any current or future relationships with any organisations.

Delivery partner organisations

The delivery partner organisation representatives will be provided with an information statement outlining the study procedures. The organisation representatives will have time to read the participant information sheet and discuss any study related questions with the research team at the University of Sydney. Consent to participate in the *Choose to Move* program will be obtained by the research manager at the University of Sydney. The organisation representatives will be made aware that the decision to participate will in no way influence any current or future relationships with the University of Sydney.

Activity coaches

All activity coaches undergoing the *Choose to Move* training will be provided with a participant information statement outlining the study procedures. The activity coaches will have time to read the participant information sheet and discuss any study related questions with the research team at the University of Sydney. Consent to participate in the *Choose to Move* program will be obtained by research manager at The University of Sydney not the partner organisation SHARE. Researchers will obtain online or written consent prior to any program commencement or training for each of the activity coaches. The activity coach will be made aware that the decision to participate will in no way influence any current or future relationships with SHARE or the University of Sydney.

6.7 Independent HREC approval

Not applicable.

6.8 Modifications to the protocol

It is agreed that any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines. No modification will be actioned in the research study until full approval from the HREC.

6.9 Protocol violations

We will establish an independent Data and Safety Monitoring Board (DSMB) to monitor adverse events and adherence to the study protocol to ensure participant safety. Any protocol deviations or violations will be submitted to the HREC for review. Any serious breaches will be notified by the principal investigator within 72 hours of the researcher team being made aware of the breach to the University.

6.10 Participant reimbursement

There is no participant reimbursement. Activity coaches undertaking the *Choose to Move* training will be reimbursed for their time for the program delivery (including training, preparation and feedback). Activity coaches will be paid as an employee (based on their ongoing rate) with their respective delivery partner organisation.

6.11 Continuation of therapy

Following the 3-month program, participants will continue to have access to the *Choose to Move* Facebook page, newsletters, and the website as they are public and readily available. If they have joined external classes, they can continue participating, however access to an activity coach will cease after the program finishes.

Participants will be followed up 6 months after the completion of the program to see if any activity they have commenced has been maintained (see Table 3). In addition, we will record any adverse events such as falls, musculoskeletal injury or cardiovascular events that has occurred post program that has reduced the ability to maintain being physically active.

6.12 Monitoring of the clinical trial

We will establish an independent Data and Safety Monitoring Board (DSMB) to monitor adverse events and adherence to the study 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.

6.13 Confidentiality and Privacy

To ensure confidentiality, participants enrolled into the study will be coded with a unique study ID number. The final dataset will contain de-identifiable information only. Refer to *Section 10 – Data Management*.

6.13.1 Data Collection

Data will be collected by questionnaires completed online or in paper format at baseline, 3 (at end of program) and 6-month post program 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 as outlined in section 10 Data management.

6.13.2 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 participant data is described in section 10.: 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 questionnaires will be scanned and stored digitally, and paper-based copies 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.

6.13.3 Data retention and archiving process

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 as per the University of Sydney guidelines.

7. ETHICAL CONSIDERATIONS

This clinical trial will be conducted in full accordance with the principles and standards from the Declaration of Helsinki, Good Clinical Practice (GCP) and National Statement on Ethical Conduct in Human Research 2023.

7.1 Identified risks

Participants

While the risks involved with participation in this program are extremely low, there is a slight chance that participants may experience muscle soreness if they start a new physical activity program. The Participant Information Statement (PIS) will have detailed information regarding research team contact details if any injuries or complications from the study arise. Members of the research team are experienced with assessing physical activity capabilities and advising of safety precautions, consistent with current clinical practice who will encourage participants in arranging appropriate medical treatment via their general practitioner (GP). Participants are encouraged to notify their GP before the commencement of any new exercise program (as outlined in the Get Active Form). The Choose to Move program is not an exercise program we are just educating the participants on the benefits of physical activity and encouraging participants to choose an activity they think will benefit them, so they become more active. Where appropriate, participants will be encouraged to fill in any necessary medical clearance forms required by gym/exercise classes before commencement

There is also a low risk that participants may experience emotional distress as they explore personal reasons for becoming more physically active and identify barriers/facilitators to goal setting. If this situation arises participants will be encouraged and supported by researchers and where necessary, will be encouraged to speak to their GP. Information on how to access support services (e.g., Beyond Blue, Lifeline) will be included on the PIS. The PIS will also detail that any participant has the right to not answer any question from the questionnaires or interviews if they do not wish to do so.

We also acknowledge that participation in this study requires a time cost for the participants. This has been thoroughly outlined in the PIS with the time required per study component. There is no participant costs or reimbursement for participant's time.

Delivery partner organisations/Activity coaches

While the risks involved with participation in this program are extremely low, there is a slight risk that the organisation representatives/activity coaches may become distressed or concerned by some questions in the questionnaires/interview. If this situation arises participants will be encouraged and supported by researchers and where necessary, will be encouraged to speak to their GP. Information on how to access support services (e.g., Beyond Blue, Lifeline) will be included on the PIS. The PIS will also detail that any organisation representative/activity coach has the right to not answer any question from the questionnaires or interviews if they do not wish to do so.

We also acknowledge that participation in this study requires a time cost for the organisation representatives/activity coaches. This has been thoroughly outlined in the PIS with the time required per study component.

7.2 Anticipated benefits

Participants

While we intend for this implementation study to further our knowledge about successfully implementing programs in Australia that improve physical activity levels of people aged 50 and over, we concede there is no direct evidence that participants involved in *Choose to Move* in Sydney Australia will benefit from this research. If the results show a positive effect, the *Choose to Move* program has the potential to benefit the broader community through the provision of the programs to larger numbers of people in other settings.

Delivery partner organisations/Activity coaches

Intervention delivery costs for the *Choose to Move* programs (including reimbursement for activity coach time) will be formally stipulated in the contract provided to the delivery partner organisation.

Activity coaches undertaking the *Choose to Move* training will be reimbursed for their time for the program delivery (including training, preparation and feedback). Activity coaches will be paid as an employee (based on their ongoing rate) with their respective delivery partner organisation.

7.3 Recruitment and avoidance of coercion

Advertising for participants will be undertaken through the general community via social media advertising and through our partnered community organisations as outlined in section 6.5.

The recruitment methods employed meet privacy requirements. For some participants they will have existing relationships with the partner organisation SHARE. To avoid any possibility of coercion people who wish to participate or would like to find out more information will need to provide their contact details and consent for a member of the University of Sydney research team to telephone them to discuss the program in more detail. Real or perceived coercion will be avoided as participation of this study is entirely voluntary. It will be made clear to participants that their participation is voluntary and non-participation will not affect current or future relationships with SHARE.

All activity coaches to deliver the *Choose to Move* program are currently employed as part of the research team at the University of Sydney or as group fitness leaders at SHARE. No extra recruitment will be necessary.

7.4 Voluntary informed consent process

Participants

Voluntary informed consent from participants to take part in the *Choose to Move* program will be obtained by researchers at the University of Sydney not the partner organisation SHARE to avoid any coercion. It will be made clear that their participation is voluntary and non-participation will not affect current or future relationships with any organisations. The participant will receive a copy of the Participant Information Sheet and will be encouraged to read and discuss the study with family, friends, and their local doctor and attend an information session (1-2 weeks prior to the program commencement). This process above is compliant with the guidelines outlined in the NHMRC National Statement on Ethical Conduct in Human Research.

Delivery partner organisations

The delivery partner organisation representatives will be provided with an information statement outlining the study procedures. The organisation representatives will have time to read the participant information sheet and discuss any study related questions with the research team at the University of Sydney. Consent to participate in the *Choose to Move* program will be obtained by research manager at The University of Sydney. The organisation representatives will be made aware that the decision to participate will in no way influence any current or future relationships with the University of Sydney.

Activity coaches

Choose to Move activity coaches will be provided with a participant information statement outlining the study procedures. They will have time to read the participant information sheet and discuss the study with the research team at the University of Sydney. Consent to participate in the *Choose to Move* program will be obtained by researchers at The University of Sydney not the partner organisations. Researchers will obtain online or written consent prior to any program commencement or training for each activity coach participant. The activity coach will be made aware that the decision to participate will in no way influence any current or future relationships with SHARE or the University of Sydney.

7.5 Participant confidentiality

All participants, delivery partner organisation representatives and activity coaches enrolled into the study will be coded with a unique study ID number. To ensure confidentiality, the final dataset will contain de-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.

7.6 Data considerations

De-identified 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.

8. SAFETY CONSIDERATIONS

8.1 Adverse event definitions

Adverse events (AEs) are defined as “incidents in which harm resulted to a person receiving health care”. For this research study, 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 categorised 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 staff member witnessing or becoming aware of a participant reporting an AE. 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 any Adverse Events (AE) in the questionnaire completed at the 3 months (completion of program) and 9 months (6 months post completing the program) follow up.

8.4 Adverse event reporting for serious or significant adverse events

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

9. OUTCOMES

9.1 Primary outcome

The primary outcome physical activity will be assessed using the single item measure of self-reported number of days engaging in at least 30 minutes of moderate physical activity¹².

9.2 Secondary outcome(s)

The self-reported secondary outcomes will be assessed at baseline, 3- and 9-months post baseline using self-report questionnaires and will take approximately 20 minutes to complete. The Short Physical Performance Battery will be assessed at the beginning and end of the 3-month program for the face to face participants. Table 5 presents the outcome measures.

Table 5: Study outcomes and measures

Secondary effectiveness outcomes	Measure
Physical activity- participation in muscle strengthening activity	Single item question: <i>How many days per week do you do muscle strengthening activities, such as resistance training with weights or bodyweight exercises?</i>
Physical activity- participation in functional mobility and balance activity	Single item question: <i>How many days per week do you do activities that emphasise balance and functional mobility training, such as yoga or Tai Chi or home exercises?</i>
Health limitations affecting activities	Short Form 36 health survey
Ability to walk 400m	Self-reported question: <i>Do you have any difficulty walking 400m (that is 2 to 3 blocks) outside on a level ground? (If yes, how much difficulty? Some, Much or Unable to do)</i>
Ability to climb 1 flight of stairs	Self-reported question: <i>Do you have any difficulty walking up 10 steps, that is about one flight, without resting? (If yes, how much difficulty? Some, Much or Unable to do)</i>
Falls and injuries	Number of falls in past 12 months and any fall-related fractures?
Sedentary behaviour	Sedentary behaviour questionnaire
Quality of life	EuroQol EQ-5D-5L
Social Isolation	Social isolation questionnaire
Loneliness Questionnaire	Loneliness lifestyle questionnaire
Balance	Perception of balance: <i>(“Do you feel your balance is excellent, very good, good, fair, poor”)</i>
Fear of falling	<i>(“Are you afraid of falling? (1 = not at all, 2 = little bit, 3 = moderately, 4 = quite a lot, 5 = extremely”)</i>
Adverse Events (measured at follow-up 3 and 9mths only)	Experience any adverse events due to becoming more physically active? Any new or pre-existing condition have resulted in you unable to be physically active?
Short Physical Performance Battery (Face to face participants only)	The Short Physical Performance Battery (SPPB) is an objective assessment tool for evaluating lower extremity functioning.

In addition to the baseline survey participants will complete a demographic and get active form to determine if it is necessary for them to seek further advice from their doctor before becoming more physically active. This information captured will inform us what type of physical activities could be suitable for them during their action plan meeting.

Cost-effectiveness

The intervention and implementation costs will be used to create a decision analytic model to conduct a simulated cost-effectiveness analysis. The cost of delivering the program will be estimated based on trial records where the resources required to implement the program will be recorded (e.g. staff time, any additional non-staff resources) and costed using appropriate wage rates and other relevant cost data.

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 algorithms¹³.

Quality-adjusted life years (QALYs) will be calculated using the health utility score at baseline, and at the 3 and 9-month follow-up. The number of QALYs gained or lost over the 3 and 9 months of follow-up will be calculated by multiplying the time spent in the health state by the relevant health utility score.

Implementation evaluation

Our implementation aims to assess:

- Readiness of delivery partners to implement the *Choose to Move* program.
- Implementation outcomes and determinants that influence implementation of the *Choose to Move* program.

Methods

For this evaluation we will interview and survey delivery partner organisations, activity coaches and participants.

Activity Coaches

We will survey activity coaches to assess five implementation outcomes (effects of deliberate actions to implement; adoption, reach, dose delivered, fidelity and participant responsiveness) and the contextual factors that influence implementation (determinants: feasibility, acceptability, appropriateness) (see Table 6).

To supplement the survey data, we will conduct interviews with all the activity coaches involved in implementing the intervention to collate experiential views about what worked well and areas for improvement (lasting up to 60 minutes). The relationship between insights gained from qualitative analysis and trial outcomes will be explored. Audio recordings (if conducted face to face) or the audio recordings extracted from the video recordings (if completed over Zoom) will be transcribed verbatim by a professional transcription service, REV (rev.com). Video recording will be deleted immediately after the zoom session and only the audio files kept for transcription.

Delivery partner organisation SHARE

To better understand delivery partner organisation SHARE's concepts of implementation strategies designed to build readiness were appropriate and effective, we will conduct a feedback survey and an interview over the phone from the organisation SHARE representative (Director/manager) after final program delivery.

Table 6: Implementation outcomes and determinants

Outcomes	Definition as per McKay et al 2019 ¹⁴	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
Fidelity	The extent to which an intervention is implemented as it was prescribed in the intervention protocol - by the delivery team	Study specific records to determine extent to which the intervention was delivered as per protocol and extent of delivery if implementation strategies (Table 4)

Dose (delivered)	Intended units of each intervention component delivered to participants by the delivery team	Study specific records to measure the intervention dose delivered and does of implementation strategies delivered (Table 4)
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 number who attended sessions 3. Quantitative survey rating different elements of intervention; 4. 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 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)
Potential for Scale-up	The scalability (the ability of a health intervention shown to be efficacious on a small scale and/or under controlled conditions to be expanded under real world conditions to reach a greater proportion of the eligible population while retaining effectiveness of a discrete health program or intervention	Intervention Scalability Assessment Tool (ISAT) ¹⁵

Participants

In terms of acceptability, barriers and facilitators, participants' experiences of the program will be explored via post-intervention 'Impressions' surveys (sent to all participants after the 3-month program) and via 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 will cover attractions and expectations of the program, views of the program and its components, any impacts, accounts of continuing/discontinuing participation, and questions related to the underlying program theory phrased in lay language. Qualitative data from free text comments in the surveys, and from transcriptions of the semi-structured interviews, will be analysed thematically.

It is estimated 20-30 participants will be invited to participate in a 30–40-minute telephone interview by a member of the research team who has experience in qualitative methods, after the completion of the 3-month study period. Participants will be informed at the beginning of the interview that it will be audio recorded. All interviews will be audio recorded and transcribed verbatim by a professional transcription service, REV (rev.com) and securely stored on the University of Sydney password protected research data store (RDS). Once the interviews are transcribed the audio files will be destroyed securely as per the University of Sydney guidelines. Participants will have the opportunity to review their individual responses after the transcription has been completed if they wish. If the program is effective, this process evaluation information will be used to guide future design for implementation at scale, including approaches for different participant profiles and contexts.

Delivery partner organisation representatives/Activity coaches

Questions in the follow up survey and interviews will be completed by all activity coaches and the representative SHARE organisation directors/managers. The topics will cover facilitators and expectations of the program, views of the program components, the impact of the program, accounts of continuing/discontinuing participation in program and questions related to the underlying program theory. All surveys and interviews will be phrased in lay language. Qualitative data from free text comments in the surveys and from transcriptions of the semi-structured interviews will be analysed thematically.

It is estimated up to 5 activity coaches and 2 organisation directors/ managers will be invited to participate in a 30–40-minute telephone interview by a member of the research team who has experience in qualitative methods, after the completion of the study period. They will be informed at the beginning of the interview that it will be audio recorded. All interviews will be audio recorded and transcribed verbatim by a professional transcription service, REV (rev.com) and securely stored on the University of Sydney password protected research data store (RDS). Once the interviews are transcribed, the audio files will be destroyed securely as per the University of Sydney guidelines. Activity coaches/delivery partner organisation representatives will have the opportunity to review their individual responses after the transcription has been completed if they wish. If the program is effective, this process evaluation information will be used to guide future design for implementation at scale, including approaches for different participant profiles and contexts.

10. DATA MANAGEMENT

10.1 Data collection

All participants, delivery partner organisation representatives and activity coaches enrolled in the research study will be coded with a unique study ID number. Participant data will be collected electronically via the Redcap system or on paper-based questionnaires. Telephone and focus group interviews will be audio recorded to capture participants, and activity coaches' 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. Our research data management plan (RDMP) is in accordance with the University of Sydney Research Data Policy.

10.2 Data storage

Data Collection forms will be stored at the following secure 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. Any paper-based consent form or questionnaires will be scanned and stored digitally on the University of Sydney password protected research data store (and deleted from the local drive), and the paper-based copies destroyed. Quantitative measures taken at face-to-face classes will be scanned and stored digitally and paper-based copies 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 an experienced qualitative researcher from the research team. Telephone interviews will be audio recorded to capture participants' views accurately. The audio files will be stored on the University of Sydney password protected research data store (RDS) and deleted from the local drive. Once the interviews are transcribed the audio files will be destroyed securely as per the University guidelines.

Regarding the audio recording data from the interviews and the use of the REV transcription service, the REV transcription service has transcribers sign NDAs and strict confidentiality agreements. Rev transcribers work on Rev's secure platform which complies with internationally recognised and industry-specific security and privacy standards, including SOC2 Type II standards in which an independent auditor assesses their data systems with regard to protection against unauthorised access. Their SOC2 Type II report shows that REV's access controls will prevent potential system abuse, theft or unauthorized removal of data, misuse of software, and improper alteration or disclosure of information. Communications with Rev servers are encrypted via industry best-practices (HTTPS and Transport Layer Security 1.2).

REV stores their data in the United States of America. REV customers can purge video, audio and document data from REV systems at any point via user interface and can set up automated deletion policies. We will set up an automation so that no data is kept by REV once the transcript has been assessed (usually less than 24 hours).

Access to the electronic stored data will be limited to authorised study staff and investigators who 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.

10.3 Data retention and archiving process

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 as per University of Sydney guidelines.

10.4 Data usage (confidentiality and sharing)

To ensure confidentiality, 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.

11. TIMELINES / MILESTONES

The study is expected to take four years to complete. We aim to recruit 10 participants for each class over the first 2.5 years of the study. This will allow time to complete the 6-month post program completion follow-up and data analysis within the 5-year grant timeframe, as outlined in Table 1. We have research physiotherapists from the University of Sydney and 5 SHARE group fitness leaders available to be the activity coaches on the *Choose to Move* program.

12. FINANCIAL

The National Health and Medical Research Council Grant (APP 2018862) is funding the study outlined. The amount awarded was \$1,212,853. Chief Investigator Prof Anne Tiedemann from the University of Sydney, Institute for Musculoskeletal Health receives and manages the funding for the grant and will be responsible for the budget of the study.

13. PUBLICATION POLICY / DISSEMINATION OF RESULTS

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.

14. REFERENCES

1. World Health Organization. Fact sheets - Ageing and health. 2021; Available from: <https://www.who.int/news-room/fact-sheets/detail/ageing-and-health>.
2. Australian Bureau of Statistics, ABS: (Explore Data) Projected persons, by living arrangement, Australia, 2016 to 2041. 2019.
3. Australian Bureau of Statistics (2020-21), Physical activity, ABS Website, accessed 7 November 2023.
4. Das P, Horton R. Physical activity-time to take it seriously and regularly. *Lancet*. 2016; 1254-1255.
5. Dwyer T, Pezic A, Sun C, et al. Objectively Measured Daily Steps and Subsequent Long Term All-Cause Mortality: The Tasped Prospective Cohort Study. *PLoS one*. 2015;10:e0141274.
6. Franke T, Sims-Gould J, Nettlefold L, Ottoni C, McKay H. Choose to Move: A Health Promoting Physical Activity Intervention Can Also Enhance Social Connectedness. *BMC Public Health*. 2021 <https://doi.org/10.21203/rs.3.rs-65551/v1>
7. O'Rourke HM, Collins L, Sidani S. Interventions to address social connectedness and loneliness for older adults: a scoping review. *BMC Geriatr*. 2018;18(1):214.
8. Ernst JM, Cacioppo JT. Lonely hearts: Psychological perspectives on loneliness. *Appl Prev Psychol*. 1999 Dec;8(1):1–22.
9. Hawkey LC, Thisted RA, Cacioppo JT. Loneliness predicts reduced physical activity: Cross-sectional & longitudinal analyses. *Heal Psychol*. 2009;28(3):354–63.
10. Patterson AC, Veenstra G. Loneliness and risk of mortality: A longitudinal investigation in Alameda County, California. *Soc Sci Med*. 2010 Jul;71(1):181–6.
11. Gardiner C, Geldenhuys G, Gott M. Interventions to reduce social isolation and loneliness among older people: an integrative review. *Health Soc Care Community*. 2018 Mar;26(2):147–57.
12. Milton K, Bull FC, Bauman A. Reliability and validity testing of a single-item physical activity measure. *Br J Sports Med*. 2011 Mar 1;45(3):203–8.
13. Norman R, Cronin P, R. V. A pilot discrete choice experiment to explore preferences for EQ-5D-5L health states. *Appl Health Econ Health Policy*. 2013;11(3):287-98.
14. McKay, H., Naylor, P.J., Lau, E. *et al*. Implementation and scale-up of physical activity and behavioural nutrition interventions: an evaluation roadmap. *Int J Behav Nutr Phys Act* **16**, 102 (2019). <https://doi.org/10.1186/s12966-019-0868-4>
15. Milat, A., Lee, K., Conte, K. *et al*. Intervention Scalability Assessment Tool: A decision support tool for health policy makers and implementers. *Health Res Policy Sys* **18**, 1 (2020). <https://doi.org/10.1186/s12961-019-0494-2>

15. APPENDICES

1. Choose to Move Protocol V3 02.09.2024_Final
2. CTM_Participant PIS_V2_02.09.2024_Final
3. CTM_Consent form_V2_02.09.2024_Final
4. Choose to move flyers V2 dated 02.09.2024
5. CTM_ScreeningTool_V1_19.07.2024_Final
6. CTM_Demographic form_V1_19.07.2024
7. CTM_Get Active form_V2_02.09.2024
8. CTM_BaselineSurvey_V1_19.07.2024_Final
9. CTM_3Mth_Survey_V1_19.07.2024_Final
10. CTM_6Mth Post program Survey V1_19.07.2024_Final
11. CTM_SPPB V1_19.07.2024_Final
12. Choose to Move_social media recruitment text_V1_19.07.2024
13. Participants Impressions of CTM_V1_31.07.2024
14. Participant Interview guide_CTM_V1_31.07.2024
15. CTM_Information session_handout V1 19.07.2024
16. ChoosetoMove (redcap survey) V1 dated 19.07.2024
17. Choose to Move Activity Coach Feedback Survey V1 31.07.24
18. Activity Coach Training Survey Version 1 dated 31.07.24.
19. Interview guide for Activity Coaches_CTM_V1_31.07.2024
20. Interview guide for Organisation_CTM_V1 31.07.24
21. Choose to Move Organisation Feedback Survey V1 31.07.24
22. CTM_tracking checklist for research manager V1 dated 7.8.24
23. CTM_PIS_Delivery Partner Organisations_V1_07.08.24
24. Choose to Move Consent form Activity Coach, Version 2, 02/09/2024
25. Choose to Move Consent form Delivery partner organisations, Version 1, 07.08.2024
26. CTM GM2 PhysicalActivity Slides V1 040924
27. CTM GM1 Tell Me About Yourself V1 09.08.2024
28. CTM GM2 Physical Activity Slides V1 04.09.2024