

Feasibility and acceptability of an evidence-based, pilot randomised controlled trial to improve health outcomes and reduce dementia risk in people with osteoarthritis. Study protocol for the Healthy Body & Mind Program (HBMP)

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Abstract

Methods: Twenty consenting participants aged 45 years and over, with OA and cognitive decline will be randomly allocated to the 12-week program or a wait-list control group. The trial is registered at clinicaltrials.gov, registration number: NCT06070818 (6th October 2023). Feasibility and acceptability will be assessed by retention and adherence rates to the program, the number of people who consent to take part in the study, and evaluation questions following completion of the program. Health outcomes will include quality of life, cognition (global, attention, learning, memory), pain, psychological health (stress, anxiety and depression) and physical health.

Ethics and dissemination: This study has been reviewed and approved by the University of New South Wales Human Research Ethics Committee (HREC: HC230506). This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). The study's findings will be published in peer-reviewed journals and disseminated at national and international conferences and through social media. Participant confidentiality will be maintained in line with ethical procedures.

Conclusion: This protocol reports methods to determine feasibility, acceptability and preliminary health outcome data of a Healthy Body & Mind Program informed by consumers with lived experience of dementia and OA.

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Original Manuscript

Research Protocol

Feasibility and acceptability of an evidence-based, pilot randomised controlled trial to improve health outcomes and reduce dementia risk in people with osteoarthritis. Study protocol for the *Healthy Body & Mind Program (HBMP)*

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Abstract

Introduction: Fifty-five million people worldwide are living with dementia. Osteoarthritis (OA) occurs in half of older adults and is associated with pain, depression and increased dementia risk. Currently, no program exists for people living with OA and cognitive decline that addresses modifiable risk factors such as physical inactivity and lifestyle behaviours. This study will examine feasibility, acceptability and health outcomes following a 12-week *Healthy Body & Mind Program* designed for people with OA and cognitive decline. Findings will inform designs for larger trials.

Methods: Twenty consenting participants aged 45 years and over, with OA and cognitive decline will be randomly allocated to the 12-week program or a wait-list control group. The trial is registered at clinicaltrials.gov, registration number: NCT06070818 (6th October 2023). Feasibility and acceptability will be assessed by retention and adherence rates to the program, the number of people who consent to take part in the study, and evaluation questions following completion of the program. Health outcomes will include quality of life, cognition (global, attention, learning, memory), pain, psychological health (stress, anxiety and depression) and physical health.

Ethics and dissemination: This study has been reviewed and approved by the University of New South Wales Human Research Ethics Committee (HREC: HC230506). This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). The study's

findings will be published in peer-reviewed journals and disseminated at national and international conferences and through social media. Participant confidentiality will be maintained in line with ethical procedures.

Conclusion: This protocol reports methods to determine feasibility, acceptability and preliminary health outcome data of a Healthy Body & Mind Program informed by consumers with lived experience of dementia and OA.

Strengths and limitations of this study

- The first stage of the study involved conducting interviews with people with lived experience of osteoarthritis and dementia to inform the design of the Healthy Body & Mind Program. Their recommendations were incorporated into the final design of the program.
- In the second stage, participants will be recruited to complete a pilot randomised controlled trial. Feasibility and acceptability will be examined. Health outcomes including quality of life, pain, cognition, psychological and physical health will be compared pre/post intervention and between program/control groups. Following the program, participants will take part in interviews or focus groups to determine acceptability of the program and investigate the views of participants, including their recommendations for future programs.
- In the third stage, stakeholder workshops with consumers, healthcare providers and policy makers will take place to discuss future implementation of similar programs at a larger scale with broader outreach.
- Recruitment and feasibility challenges may impact the success of the trial. Mitigation strategies include considering language use on recruitment materials, advertising the trial widely using multiple recruitment platforms and healthcare contacts, and ensuring smooth communication processes between researchers and participants.

Keywords: cognitive decline, dementia, depression, education, exercise, lifestyle,

Introduction

Fifty-five million people worldwide are living with dementia(1). Osteoarthritis (OA) is experienced by 528 million people worldwide(2) and is associated with a 20 to 25 percent increase in dementia risk(3, 4). Prevalence of OA has been reported in almost half of people living with dementia(5, 6). Both dementia and OA are associated with increased pain and depression(7-9), and reduced quality of life (QoL)(8, 10). Comorbid conditions such as OA, depression and dementia exacerbate symptoms, for example a higher number of comorbidities (i.e., multimorbidity) correlate with more severe pain and depression(11).

Reduced quality of life (QoL), depression and anxiety are common in dementia(9, 12) and OA(13), in addition to pain(7). Further, OA has been associated with a 1.2- to 1.5-fold increase in dementia risk(14) and rises to 5.7-fold when experienced with an additional chronic condition(15). However, most older adults, including people living with cognitive decline, are living with comorbid conditions such as OA(16, 17). Depression and anxiety are also commonly comorbid with cognitive decline(18) and OA, and depression has also been linked with increased dementia risk(19).

Nonpharmacological lifestyle approaches involving physical activity (PA) have been shown to improve health outcomes for 26 different chronic conditions(20), including dementia(21) and OA(7). OA and other chronic conditions are associated with increased dementia risk(21, 22), and physical activity and other nonpharmacological approaches improve health outcomes in older adults whilst reducing dementia risk(21). Physical activity interventions improve cognition in people living with dementia(23), as well as reduce dementia risk in older adults(21). Studies have shown that PA and lifestyle approaches reduce dementia risk(15, 21, 24) and improve cognition and QoL for people already living with cognitive decline(25-27). Further, nonpharmacological approaches have been shown to be cost-effective(28) and preferable to pharmacological approaches for people living with dementia and their families/care partners(29).

Systematic reviews have shown that physical activity has a positive effect on cognition(30), depression and quality of life(31). Though findings are inconsistent regarding the best type of physical activity. Multimodal and/or mind and body focused approaches tend to out-perform singular, or unimodal approaches(31). Interventions shown to be effective in reducing pain in OA include aerobic and strengthening exercise and multimodal approaches that incorporate lifestyle education specific to OA, such as pain coping skills training(32). Multimodal approaches have been shown to be more effective than unimodal approaches in reducing pain(7) and improving depressive symptoms. Physical activity has positive effects on mental health(33) and improves outcomes for older adults living with anxiety and depression. Meta-analyses have shown that nonpharmacological approaches reduce symptoms of depression in people living with cognitive decline(9) and OA(7). Nonpharmacological approaches include care staff education and reminiscence therapy for people living with dementia, and multi-modal exercise approaches (i.e., combined strength, balance, aerobic and mind-focused approaches such as Tai Chi and yoga) for people with OA.

Despite this evidence, there is a lack of assessable, implementable and scalable lifestyle programs for people living with comorbid conditions such as cognitive decline and OA. This gap reflects a major opportunity for improving health outcomes and reducing dementia risk. Guidelines for multidisciplinary approaches that include PA have been developed for people living with cognitive decline(34, 35), but effective interventions are specifically needed to target people living with comorbidity(16, 36) and to reduce dementia risk. It is vital to consider associations between conditions and how symptoms may be exacerbated (e.g., symptoms of depression resulting from limitations in completing usual daily activities due to OA-related pain and/or thinking difficulties).

Therefore, we will pilot an evidence-based, Healthy Body & Mind Program (HBMP) that includes physical activity, nutrition, lifestyle and behaviour change education on health outcomes in people living with cognitive decline and OA. The evidence base for development of the program is outlined in Figure 1. The primary aims of this pilot randomised trial are to determine: (1) the feasibility (i.e., recruitment, retention, adherence) of the HBMP for people living with OA and cognitive decline in a community clinic, the UNSW Medicine & Health Lifestyle Clinic, Sydney, Australia; and (2) the acceptability of the program to people living with OA and cognitive decline. The secondary aim is to obtain pilot data on health outcomes in people living with OA and cognitive decline, following the program when compared to usual care. Health outcomes are quality of life (QoL), cognition, pain, psychological health (depression, anxiety and stress) and physical health (weight, waist circumference, blood pressure, cardiorespiratory fitness, strength, mobility and balance). We hypothesise that individuals who complete the program will have better health outcomes when compared to baseline and the control group.

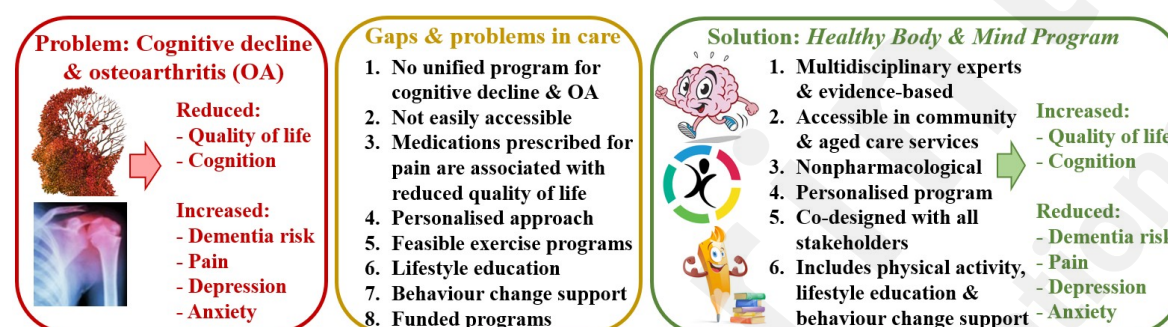


Figure 1. Evidence-based conceptualisation illustrating how the *Healthy Body & Mind Program* (HBMP) will improve health outcomes for people with cognitive decline and OA in community settings.

Methods

Ethical approval for the study has been obtained from the University of New South Wales Human Research Ethics Committee (HC230506). This protocol document is Version 3 and aligns with approved ethics amendments (most recently approved 14/06/2024; first approval on 18/09/2023). Changes from the first version were made to the inclusion criteria where 'Montreal Cognitive Assessment (MoCA)(37) score 18-25 indicating mild cognitive impairment or mild dementia' was removed and the age requirement was reduced to 45 years and older. These changes were made due to recruitment challenges though do not change the overall aims of the study. Other amendments were made to terminology ('dementia', 'cognitive decline', and 'thinking difficulties' to improve recruitment) and staff members. All team members received email correspondence regarding submitted changes and were requested to review amended documentation where appropriate. The clinical trial has been prospectively registered at <https://clinicaltrials.gov/> (NCT06070818). The protocol has been prepared in accordance with the SPIRIT guidelines (Standard Protocol Items: Recommendations for Intervention Trials) (Appendix 1)(38).

Study design

This 12-week pilot randomised controlled trial (RCT) of the *HBMP* with wait-list control group will use quantitative and qualitative research methodology. Data collection will comprise: (1) clinical observations routinely completed as part of standard care (clinical interviewing, physical assessment, exercise monitoring), (2) validated patient-reported outcome measures (including QoL, cognition, pain and psychological health), and (3) focus group/interviews (Table 1). Clinical observations and questionnaires will be completed at baseline (0 weeks) and post-intervention (12 weeks). Initial community and stakeholder engagement has assisted with developing the group

program and ensuring it is feasible and acceptable to participants. The study team includes accredited exercise physiologists (AEPs), accredited practicing dietitians (APDs), a health psychologist and research assistants (RAs). All study activities will take place within the UNSW Medicine & Health Lifestyle community Clinic facilities, UNSW Sydney, Australia.

Sample size calculation

For pilot trials, using an 80% one-sided confidence interval, it is estimated that a sample size should be at least 9% of that calculated for a fully powered RCT(39). Given a minimal clinically important difference (MCID) of 0.5 SD (medium effect size), quality of life measured using the SF-36 (40, 41), significance level: $\alpha = 0.05$ with Holm-Sidak correction; power: 80% ($\beta = 0.20$), for a two-group comparison, the required sample size would be approximately 64 participants per group (128 total). Accounting for potential dropout/attrition (15-20%), 77 participants per group ($n=154$ total) would need to be recruited for a fully powered trial and 14 participants would be required for a pilot trial. This study aims to recruit 20 participants.

Eligibility criteria

Eligibility criteria will be: 1) aged 45 years or over, 2) living with OA diagnosed by a healthcare professional, 3) living with thinking concerns/dementia, 4) able to safely undertake study assessments and complete exercise without assistance, and 5) have appropriate medical clearance to take part. Exclusion criteria will be: 1) MoCA score <18 , 2) unwilling or unable to provide written informed consent and comply with study requirements, 3) inability to speak and understand English, unless a translator is available, and 4) contraindications to exercise in accordance with ACSM guidelines (Appendix 2)(42).e.g., symptomatic hernias, proliferative retinopathy, uncontrolled arrhythmias or rapidly progressing or terminal illness). Consent will be obtained by the lead researcher (CB).

Recruitment

Twenty participants living with cognitive decline and OA will be recruited through the UNSW Medicine & Health Lifestyle Clinic, StepUp for Dementia Research, and through General Practitioner (GP) and Health District referrals. Study advertisements will also be displayed electronically through online social media (e.g., Twitter, Facebook, LinkedIn). Initial contact will be made by potential participants emailing the study investigators through the study email or StepUp team, or by referral from a health professional. A member of the research team will then contact potential participants. Participants will be screened in-person, online or over the telephone to confirm their eligibility. The lead investigator will review participants screening data and confirm participants eligibility prior to providing the Participant Information Sheet and Consent Form (PISCF) (Appendix 3). If eligible and after written consent has been obtained, potential participants will be invited to an in-person screening visit. Demographic information, chronic disease history, lifestyle behaviours and medication use will be documented. Potential participants will undertake pre-exercise APSS and ESSA(43) screening questionnaires about exercise-induced symptoms (e.g., chest pain, musculoskeletal pain; Appendix 4). To ensure safety, only people cleared through the screening will be enrolled and randomised. Once deemed eligible, participants will complete written informed consent and baseline testing will commence. Participants will be assigned a unique identification number to ensure personal details are not linked to collected data.

Due to ethical considerations where many potential participants may not be aware of cognitive decline, the term 'thinking difficulties' will be used throughout study advertisements and participant information sheets. An ethically approved protocol is in place for advising people of their health assessment results (e.g., cognition, depression) and referring them to their general practitioner where appropriate. Eligible participants will have mild cognitive impairment, therefore will have capacity to provide informed consent.

Following successful screening, the participant will be allocated a unique-identification number,

using the generated list. The RA who performs the randomisation will advise the data collectors of the persons ID by referring to the password protected spreadsheet of participant names and allocated ID numbers. After completion of baseline testing, participants will be randomly assigned to the intervention (n=10) or wait-list control (n=10) using a computer-generated randomisation list produced by a researcher external to the study group. In total 20 participants will complete the program. After completing a 12-week period of usual care, those in the wait-list control group will then complete the 12-week HBMP. A 12-week follow-up will be performed to examine sustainability. Participants were allowed to withdraw from the trial at any time they wished and were ensured this would not alter their care, or relationship with the university and/or the community clinic.

Data collection and outcome measures

Feasibility and acceptability

The feasibility of the program will be determined by the number of eligible participants who provide consent, retention and adherence to the program (i.e., number of exercise and education sessions attended, completed and engaged with). Retention will be determined by the percentage of consented participants who complete the program. Adherence will be determined by the percentage of program sessions attended by participants who enter the program. Adherence will be recorded using attendance records (recorded by the AEP and health psychologist facilitating the sessions). The acceptability of the program will be assessed by post-program evaluation questionnaires after the program has been completed.

Health outcomes

Baseline and post-intervention assessment visits will take between 90 and 120 minutes including the health interview, physical assessment, and questionnaire completion. The research assistant completing assessments will be blind to the condition (intervention/wait-list control). The research assistant will be trained and supervised by an AEP.

Secondary outcome measures will be completed prior to randomisation at baseline, and at 12 weeks post-intervention. The outcome measures (questionnaires outlined in section 2.5.2 below) will be completed by a RA and member of the research team who is blind to group allocation. Health outcome measures will include QoL (measured using the SF-36)(44), cognition (MoCA)(37) and the Cambridge Neuropsychological Test Automated Battery (CANTAB) attention, learning and memory tasks, pain (Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC))(45, 46), psychological health (depression, anxiety and stress scale (DASS 21)(47)) and physical health (weight, waist circumference, blood pressure, functional fitness, strength, mobility and balance). Balance exercises will be simple, easy to perform movements that take place in a purposefully set-up environment that minimises the risk of falls (i.e., they will be beside a wall, an AEP will be closely monitoring them, the simple exercises will be completed first, enabling the AEP to continually assess whether it is safe for the participant to continue to the slightly more challenging balance exercises).

The questionnaires (listed in Table 1) will assess the participants' health relevant to the outcome measures (e.g. cognition, QoL, psychological health). The data collection process will be administered using UNSW Qualtrics except for the cognition measures, as these require the participant to draw onto the printed tool (i.e., pen and paper questionnaire). Participants will be asked the questions by an experienced health psychologist and RA who has experience interviewing people with cognitive decline. They will enter the data directly onto a tablet or onto paper for the MoCA (with no identifying information, just a participant ID). The MoCA data will then be entered electronically. The health psychologist has received appropriate training to administer the MoCA(37) and a licence (obtained July 2022 from <https://mocacognition.com/>) and permission to train other staff and students to administer the tool. Participants will be invited to bring a support person with them if they wish, given that variability in level of independence is expected in this

population (people living with cognitive decline and OA). All questionnaires have been validated and used extensively in the literature and with clinical populations, including people with osteoarthritis and cognitive decline.

Data management

The questionnaires will be completed within the UNSW Lifestyle Clinic facilities. The data captured on Qualtrics and the CANTAB software using a computer or tablet will be exported to Excel and SPSS for data analysis and stored on a secure OneDrive database hosted by UNSW Sydney. The data will be entered, checked and cleaned by two members of the research team. Only members of the research team will have access to the data. All recruited participants will be assigned a unique study identification number, ensuring no personal details such as their name, are stored alongside data.

Table 1. Data collection methods and outcome measures

1. Clinical assessments (resting cardiovascular and anthropometry measures)	
Measure	Procedure (tools/guidelines)
Resting blood pressure and heart rate	Validated automated sphygmomanometer. Participants will be seated and rested for at least 10 minutes prior to the blood pressure assessment(52). Participants will place their forearm on a table with the elbow at an approximate 90° angle and the cuff placed on the upper arm according to the manufacturer's instructions. Three, separate measurements will be taken on both right and left arms, with the average of the three measurements used in subsequent analyses.
Waist circumference, height, weight, body mass index	Weight will be measured using a digital scale (Seca 813 model) with the participant unfasted, barefoot, and dressed in light clothing. Height will be measured barefoot using a SECA wall mounted stadiometer (Seca 216 Stadiometer). Waist circumference will be measured according to the International Diabetes Federation guidelines(53).
Handgrip strength	Manual dynamometer
Functional fitness	Sub-maximal 6 Minute Walk Test(54). The participant will be instructed to cover as much distance walking on flat ground in a laboratory setting until they have completed 6 minutes, or they choose to stop walking. Risk of falls will be minimised by the AEP/RA following the participant closely to enable spotting and assistance should they lose balance. They will also monitor the participant throughout the test for safety (including heart rate and rating of perceived exertion (RPE)).
Lower extremity function and mobility	Short Physical Performance Battery(55), which involves timing the duration of five sets of sit-to-stands from a chair, feet together, semi-tandem and full tandem stance and 8-foot walk
Balance	Single leg balance test. The participant will be instructed to stand on one foot for as long as possible without assistance, up to a maximum of 60 seconds. To minimise risk of falls, they will be supported by an AEP/RA and there will be a wall and/or sturdy chair in front of them they can hold onto if needed.
2. Questionnaires	
Measure/tool	Procedure (tools/guidelines)
Adult Pre-Exercise	Exercise Sports Science Australia (APSS)(43)

Screening System (APSS)	
Cardiovascular Disease Risk Estimator Plus (ASCVD)	American College of Cardiology(56)
Active Australia Survey	Australian Institute of Health and Welfare: A guide and manual for implementation, analysis and reporting
Cognition (global, executive, learning, memory, visuospatial ability)	Montreal Cognitive Assessment (MoCA)(37) Cambridge Cognition (attention, memory and learning tasks)
Pain, physical health and stiffness	Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)(45)
Depression, anxiety and stress	Depression, anxiety and stress scale (DASS 21)(47)
Quality of life	EuroQoL-5(57) and SF36 v2 Survey(44)
Self-efficacy	Ewart's Physical Exercise Self-Efficacy Scale(58)
Sleep quality	Pittsburgh Sleep Quality Index(59)
Diet	24-hour food recall, Intake 24(60)
3. Qualitative methods	
Measure/tool	Procedure (tools/guidelines)
Participant feedback and recommendations	Focus group/interviews (semi-structured questions)(61)
Consumer/ stakeholder feedback and recommendations	Stakeholder meetings/workshop (semi-structured format)
4. Adverse events	Ongoing monitoring and reporting in accordance with CONSORT guidelines (48)

Adverse events

Physical activity may cause concern in older adults and people living with chronic conditions. Adverse events may occur, e.g., a fall, despite the safety protocols we have put in place (e.g., AEP/ RA closely monitoring participant during exercise in a purposefully designed clinic/laboratory setting with handrails, etc.). Throughout the trial and follow-up, adverse events will be documented, and risk will be continually assessed by appropriately trained professionals (i.e., AEP). Reported adverse events will include details about the type of event, date, time and duration, severity (mild to severe), whether it could have been avoided, outcome (solved to fatal), and whether it was related to the study (certainly/probably/possibly/unlikely/cannot say). The relevant ethics committee and participant's general practitioner will be informed about any serious event (e.g., requiring hospitalisation) that take place during the study. Adverse events will be reported transparently alongside study outcomes. In accordance with the CONSORT statement(48) and similar to other studies(49), data from participants that are suspended from the trial due to an adverse event will be entered in the analysis by treatment allocated. The lead researcher will continue to communicate and support the participant and signpost them to relevant support services where appropriate.

Intervention

The Healthy Body & Mind Program (HBMP) has been designed according to international guidelines for prescribing exercise in older adults including the American College of Sports Medicine(42), and the lifestyle education aligned with known risk factors of dementia(21). The program will be delivered within the UNSW Medicine & Health Lifestyle Clinic facilities by an AEPs and health/clinical psychologists. The 12-week program sessions will take place twice per week (24 sessions in total) and be 60-90 minutes in duration including exercise and lifestyle and behaviour change education. Both weekly sessions will comprise 45 minutes of supervised exercise. The first weekly session will be followed by 45 minutes of education (including pain self-management, nutrition, sleep, reducing smoking and alcohol). Participants will be assigned to timeslots suitable for them at the beginning of the program to help reduce the number of missed sessions. Catch-up sessions will be available for participants where they are unable to attend their allocated slot. Four groups (2-8 participants per group) of The *HBMP* will take place over 6 months (2 groups in a wait-list control for the first 3 months). Participants can choose the days and times that suit them and will repeat those for the full 12-week program.

Exercise component

The exercise component will be evidence based and delivered using the variety of exercise equipment available within the UNSW Medicine & Health Lifestyle Clinic facilities and independent exercise. Exercises will be modified for each individual based on ability and fitness. A combination of aerobic, resistance, balance and flexibility exercises will be prescribed to suit the needs of the individual participants.

The American College of Sports Medicine (ACSM) guidelines state that older adults should aim to complete 'resistance training twice a week and aerobic exercise of moderate intensity for 150-300 minutes a week, or vigorous intensity for 75-150 minutes per week' (42, 50). Therefore, the exercise prescription guidelines shown in Table 2 will be followed. Participants will complete resistance training twice weekly at the clinic in addition to 60 minutes of aerobic activity, and 90 minutes or more of independent/home-based aerobic activity. Independent activity will be recorded each week on a printed record sheet and returned to the AEP each week on completion. This will total the ACSM's recommended 150 minutes per week of aerobic activity and two strength-based sessions that older adults should engage in for health benefits (Table 2) (42, 50). The prescriptive elements of all exercises performed will be recorded in program training sheets each session to ensure all necessary detail is captured. The education sessions will provide information on how participants can complete physical activity independently (Table 3).

The AEP and health psychologist will receive training from two of the study investigators (CB and BP) to deliver the exercise and education. Exercise monitoring observations will take place to record and assess the participants' compliance with the prescribed exercise program relevant to the secondary outcome measures. This data collection will be undertaken face-to-face during group exercise sessions. The AEP will conduct the clinical assessment and group exercise sessions. Each sessions data will be collected using program sheets already used in the clinic, to capture descriptive details of specific exercises. Measurements of heart rate, blood pressure and rating of perceived exertion (Borg Rating of Perceived Exertion(51)) will be taken during the group sessions. This data will be analysed to provide information on the overall intensity of exercise achieved in each group session.

Lifestyle and behaviour change education component

The education component will also take place at the UNSW Medicine & Health Lifestyle Clinic and involve group discussions developed by a health psychologist and delivered by a health and clinical psychologist. The education topics and resources are shown in Table 3. In summary, they include

information about living with OA and cognitive decline, physical activity, nutritional advice, psychological health, social connections, developing individual goals and action plans, and final sessions determined by individual/group preferences. Educational materials are shown in the resources column and have been developed by organisations including Dementia Australia, Arthritis NSW, Alzheimer's Association, and the Australian Government Department of Health. Printed and electronic copies will be provided to participants and used to guide discussions.

Table 2. *Healthy Body & Mind Program (HBMP)*: Clinic-based exercise component

	AEROBIC EXERCISE	RESISTANCE EXERCISE
Frequency	Twice weekly (clinic-based)	Twice weekly (clinic-based)
Duration	30 minutes	30 minutes
Intensity	Light-Vigorous (Light: RPE 8-10; Moderate: RPE 11-13; Vigorous: RPE 14-16)(50).	Light-Vigorous (Light: 30-49%1RM, RPE 9-11; Moderate 50-69%1RM, RPE: 12-13; Vigorous: 70-84%1RM, RPE 14-17).
Type	Major muscle groups: Cycling (upright/recumbent); Walking (treadmill), rowing, stepping.	Pin-loaded weight plate machines (e.g. leg press, leg extension, leg curl, seated row, chest press, latissimus ('lat') pulldown) body weight, free weights, resistance bands.
Volume	Frequency x intensity x time.	Sets x Reps x Days. 1-3 sets, 8-12 repetitions.
Pattern	One continuous bout or multiple bouts (e.g., 30 minutes or 3 x 10 minutes).	Rest between sets/exercises.
Progression	Commence first exercise session in week 1 at low-moderate intensity (50-60%HRmax, RPE 9-13) and progress gradually as tolerated by the individual.	Weights will be increased to ensure participants RPE remain within the required range.

Abbreviations: HRmax, maximum heart rate (beats per minute); RPE, rating of perceived exertion(51); RM, repetition maximum.

Table 3. *Healthy Body & Mind Program (HBMP)*: Lifestyle and behaviour change education component in accordance with leading organisations. Each session was facilitated by education slides developed by author CB.

Session topic	Resource (factsheets/guidelines) and organisation
Personalised goals and action plans	Behaviour change techniques, action planning and SMART goals(62).
Nonpharmacological approaches	Osteoarthritis (Arthritis Australia). Mild Cognitive Impairment (Dementia Australia).
Physical activity	Osteoarthritis Fact Sheet (Exercise is Medicine Australia). Physical exercise and

	dementia (Dementia Australia).
Pain neuroscience education	
Nutrition	Healthy eating and arthritis (Arthritis Australia). Food diary (to be used with Intake 24).
Psychological health	Arthritis and emotional wellbeing (Arthritis Australia). Depression and dementia fact sheet (Dementia Australia).
Social connections	Social connectedness in older adults. (Centre for Healthy Brain Ageing, American Association of Retired Persons).
Sleep	
Alcohol and smoking	
Participant's choice	

Statistical analysis and clinical interpretation

Quantitative data will be analysed using SPSS. Data will be checked for normality and reported as mean and standard deviation. Within and between group change scores will be calculated for clinical outcomes using data from baseline and post-intervention assessments. Statistical significance will be set at $p < 0.05$. Outcomes from the control group will also be analysed after they have completed the intervention. Given the small sample size and that the primary aims of this study are assessing feasibility and acceptability, confounders will not be analysed. Baseline data will be compared between control and intervention groups, to ensure there are not significant differences between groups at baseline. Feasibility outcomes will be examined in terms of frequencies and percentages (percentage of eligible participants who consent, session attendance and compliance). A note of the reasons for non-attendance will be collected and reported. Participants' perspectives on the intervention's acceptability will be based on feedback captured in the exiting Patient Experience Questionnaire and in the focus groups. Acceptability will encompass what participants liked most and least about the program and their suggestions for the content and format of the sessions. Adverse events will be recorded and ongoing monitoring and reporting will be completed in accordance with CONSORT guidelines (48).

Ethics and dissemination

The project findings will be submitted for national and international conference presentations and scientific journal publications. Findings will also be prepared appropriately for other stakeholder groups (e.g., lay summaries for people with lived experience of chronic conditions, families and the public; reports for healthcare, government and industry partners). When participants provide consent, they will be invited to indicate whether they would like to receive study findings.

Patient and public involvement

The design of the program was informed following meetings with people living with OA and dementia. Co-author William (known as Bill) Yeates is a study investigator, an expert by experience of living with dementia, and is a dedicated professional in the dementia and healthcare community. They currently serve as a Living Experience Associate Consultant at Hammond Care, are a member

of the Alzheimer's Disease International (ADI) Global Review Panel for Accreditation, Public Involvement Panel for Step-Up for Dementia Research, and SLEAP Program. They have been a member of the Dementia Australia Advocacy Program since 2020. Additionally, they hold the role of Vice Chair at Dementia Alliance International and are part of the COGNISANCE Co-design Group. Their professional engagement includes participation in numerous international and national conferences, such as the ADI Global Conferences in Krakow and London, the ADI Asia Pacific Conference in Taiwan, and various Australian conferences including the International Dementia Conference and Australian Dementia Research Forum. They have also established their own website, awakeningyourpositivity.com, to further share their insights and expertise.

Bill is a lead investigator on this project and has been involved in all stages developing this research. Pre-study consultation identified specific considerations for people living with cognitive decline and OA and different experiences and expectations of a program such as the *HBMP*. In summary, feedback included practical considerations such as transport and accessibility to take part in the program (e.g., building and environmental considerations, ease of access, lighting, etc.), the option of having a support person whilst participating in the program, ensuring the program included multiple components, though considering that individuals may differ in terms of how much support they would like to receive from each component (e.g., nutritional advice sought by some and considered less important by others), including a social component to the program or considering social factors, and ensuring a tailored approach is adopted to suit participants' unique needs. We have set up a Community Lived Experience Group of thirty people within our clinic who were invited to provide feedback on this study at the beginning of the project development. Participants and support persons will be invited to take part in a focus group or interview at the end of the pilot RCT to provide their feedback and share their experiences. These meetings and focus groups will inform the interpretation and dissemination of findings, and guide future large scale implementation.

Conclusion

This is a pilot RCT with complementary quantitative and qualitative components that aims to determine feasibility and acceptability of a 12-week Healthy Body & Mind Program. Further, we will examine whether the program improves QoL, cognition, and other health outcomes (pain, depression, physical health) in people living with cognitive decline and OA. Currently, there is no program available to meet the specific needs of this population, despite the prevalence of dementia rapidly increasing, and that half of older adults globally are living with chronic pain, often attributable to OA. The program has been developed in partnership with people with lived experience of dementia and osteoarthritis, AEPs, clinical researchers, chronic disease specialists and APDs. The program will continue to be co-developed, ensuring it is feasible in a real-world setting and easily scalable.

The range of health outcomes (e.g., QoL, pain, cognition, and other physical and psychological measures) will allow in-depth inquiry on multiple factors associated with comorbidity and dementia risk. The qualitative component will provide feedback from experts living with cognitive decline and OA regarding whether the program was enjoyable, feasible and met all their needs. A multicomponent, evidence-based program that has been informed by diverse experts including those with lived experience, may improve health outcomes for older adults living with cognitive decline and OA and reduce dementia risk.

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CB designed the study, obtained funding and ethical approval, drafted the manuscript, and will lead all activities outlined in this protocol. WY, NB & MJ and BP assisted with study design. All authors have approved the final version of this manuscript.

Conflicts of Interest

HB is or has been an advisory board member or consultant to Biogen, Eisai, Eli Lilly, Medicines Australia, Roche and Skin2Neuron. The other authors have no conflict of interest to report.

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Supplementary Files

Multimedia Appendixes

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