

Improving Mood through Physical Activity for Carers and Care recipients: Protocol for a randomised trial (IMPACCT)

Briony Dow^{1,2}, Kirsten Moore¹, Melissa Russell³, David Ames^{1,2,6}, Elizabeth Cyarto¹, Terry Haines⁴, Keith Hill^{1,5}, Nicola T Lautenschlager^{6,7}, Lynette Mackenzie⁸, Susan Williams¹ and Samantha Loi⁶

¹National Ageing Research Institute, ²The University of Melbourne, Department of Psychiatry, ³The University of Melbourne, School of Population Health, Department of Molecular, Environmental, Genetic and Analytic Epidemiology, ⁴Monash University, Department of Physiotherapy, & Southern Health, Allied Health Research Unit, ⁵Curtin University, School of Physiotherapy, ⁶Academic Unit for Psychiatry of Old Age, St. Vincent's Health, The University of Melbourne, Department of Psychiatry, ⁷School of Psychiatry and Clinical Neurosciences, & WA Centre for Health and Ageing, University of Western Australia, ⁸The University of Sydney
Australia

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Introduction

In Australia, carers save the economy in excess of \$40 billion per year [1] by providing in-home care for older people and people with disabilities, and delaying the need for residential care admission and/or government funded home care. The proportion of the population aged 65 years and older is projected to increase from 13% now to between 26% and 28% by 2051 [2], with an increase of more than 50% among those aged over 85 years with a severe or profound activity restriction [3]. Most care is provided by informal carers, usually family members, of which there are approximately 2.6 million in Australia, including 520 000 over 65 years of age [4].

Research suggests that older carers provide this care at high personal cost, with adverse effects including depression [5], anxiety [6], threats to subjective or emotional wellbeing [7, 8], and carer burden [9]. An Australian study found that over 50% of carers in their sample (n = 3766) were at least moderately depressed and only 35% were free of depression [10]. Once depressed, older people are unlikely to spontaneously recover and are at greater risk of suicide than younger people [11]. These problems, in turn, can lead to stress in the care relationship, including potentially harmful behaviour to the care recipient [12].

Negative outcomes of caring have been associated with the severity of disability and dependency of the care recipient [13-15]. Various physical activity approaches have been shown to be effective in improving the physical health of older people [16-20]. Physical activity can also provide mental health benefits to older people, including slowing the rate of cognitive decline [21] and reduced depression and anxiety [16, 22-24]. However, in these studies, the intervention has targeted individual participants. Research investigating the benefits of physical activity in the more complex situation of the carer dyad has not been undertaken to our knowledge.

While there have been a small number of intervention studies that have demonstrated improvements in carer wellbeing [25], overall there is little detailed evidence about the most suitable interventions to help carers and care recipients [26]. Carer physical activity appears to be one of the more effective interventions. Significant improvements in both physical and mental health outcomes for carers have been demonstrated in a 6-month centre-based physical activity program (strength training, yoga, or Tai Chi using a pre-post study design) [27]. Another pre-post study evaluating an exercise program for women caring for relatives with dementia conducted in the USA found promising improvements in stress, burden, and depression in the group receiving a physical activity intervention [28]. However, these studies have been conducted with a single target group (carers), did not examine joint provision of an exercise program to both the carer and care recipient, and did not examine health outcomes for both the carer and care recipient.

There are several potential benefits to providing physical activity interventions simultaneously to both the carer and care recipient. It is anticipated that encouraging the carer and care recipient to undertake the intervention together will increase motivation, compliance and be more enjoyable than sole exercise programs. The program will not require provision of respite care or transport as would a group or carer only intervention. The health professional will arguably be more efficient in assessing and delivering the program to the dyad as compared to the time taken to provide similar services to two individuals.

This paper presents the protocol for a randomised controlled trial investigating an innovative physical activity intervention designed for older carers and care recipients to undertake together in their own homes. This physical activity program aims to improve mental health and minimise functional decline amongst care recipients and carers. The primary aim of the study is to reduce carer depression. It aims to do this mainly via two pathways: first through directly reducing depression due to the beneficial effects of physical activity for the care, and

second by reducing the physical dependency of the care recipient which in turn may decrease the level of carer depression.

The research questions are:

- Will an individualised home-based physical activity program (Otago-Plus) be effective in reducing carer depression at 6-months after the baseline assessment (primary outcome)?
- Will an individualised home-based physical activity program (Otago-Plus) be effective in reducing carer depression at 12-months after the baseline assessment (primary outcome)?
- Will the Otago-Plus program be effective in improving care recipient and carer physical activity and function, and carer satisfaction (secondary outcomes)?
- Will the Otago-Plus program for older care recipients and their carers be cost effective?
- Will the Otago-Plus program be effective in reducing health service use and falls in the care recipient (secondary outcomes)?

Method

Design

The study will be a randomised controlled trial based on the CONSORT guidelines [29], incorporating an economic evaluation of outcomes. The process of assessment, randomisation, and group allocation is illustrated in Figure 1.

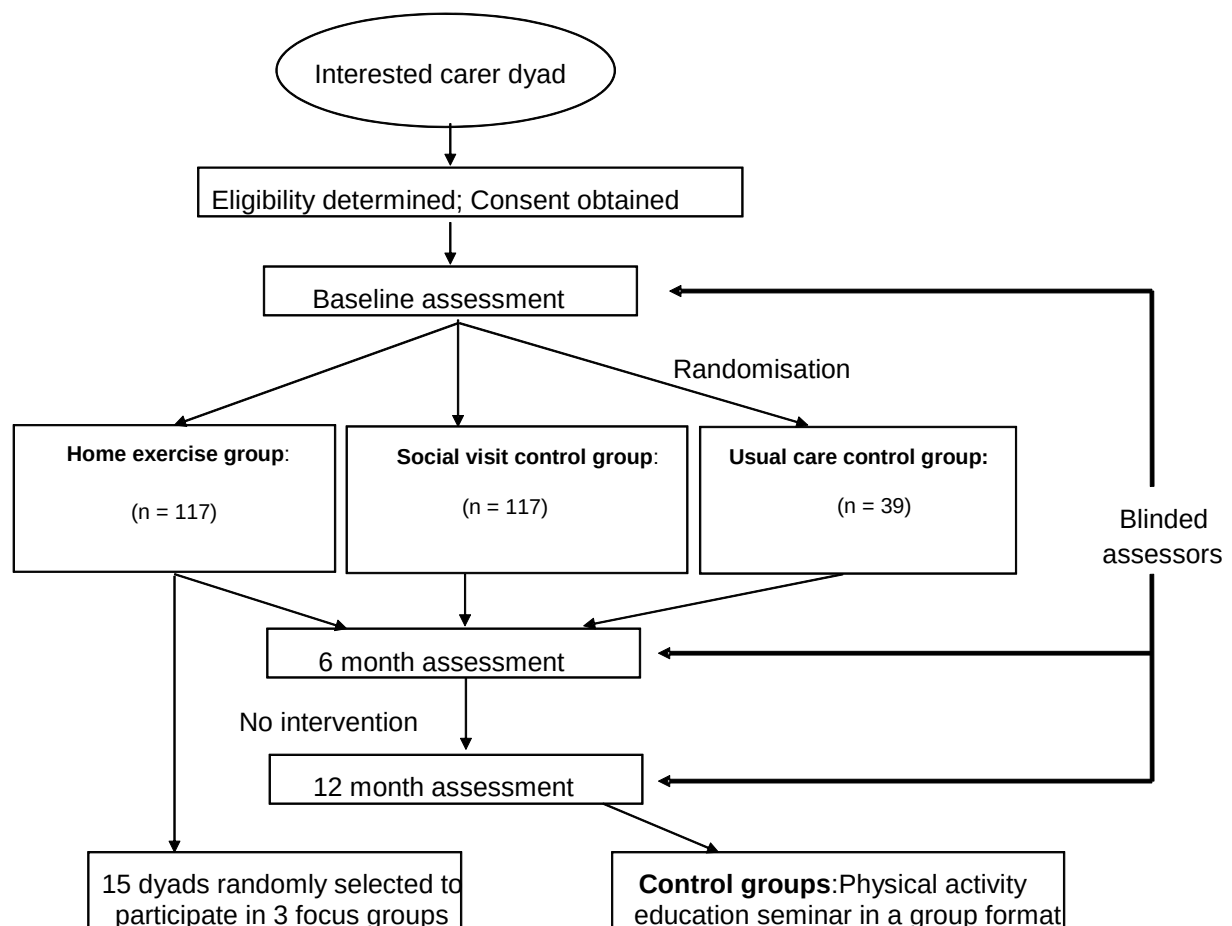


Figure 1: Diagram of participant flow through trial

Participants

Carers will be included in the study if they are: a) aged 55 years or over; b) providing informal care for a person aged 60 years or over living at home; c) living with the care recipient; and d) have a Geriatric Depression Scale (GDS) 15 score ≥ 5 . Care recipients will be included in the study if they are receiving care and support from an informal carer (with or without additional paid care and support) who has a GDS 15 score ≥ 5 . In addition, care recipients will meet the following criteria: a) aged over 60 years; b) live at home with their carer; and c) dependent in at least one activity of daily living (ADL: dressing, bathing, shopping, monitoring medication, organising, laundry, meals, decision-making, supervision, emotional support, getting around in or outside the home, getting help in an emergency).

Exclusion criteria include: carers aged less than 55 years old and care recipients aged less than 60 years old; care recipients who do not have an informal carer who lives with them; carers who do not live with the care recipient; dyads where the carer has a GDS 15 score < 5 ; and carers who cannot provide informed consent due to cognitive incapacity or other reasons.

Participants will be recruited via carer support agencies in metropolitan Melbourne and regional Victoria (Ballarat, Geelong), community aged care services, Council on the Ageing (COTA), and general media and promotion in newsletters targeting older people in Victoria, Australia. There will be an 18 month period for recruitment.

All assessments and interventions will be conducted in the carer / care recipient's home.

Intervention

Participants allocated to the intervention group will receive a visit at home by an experienced therapist (physiotherapist or exercise physiologist) for provision of an individualised home exercise program. Both the carer and care recipient will receive their own exercise program. Participants will be asked to complete the exercises 5 days a week for 6 months. The balance, strengthening, and walking exercises will be selected from the Otago exercise program [30] and the Visual Health Information Exercise Prescription Kits—Balance & Vestibular Rehabilitation set (<http://www.hprresources.com.au/>). Combining the two programs (known as the 'Otago-Plus' program) will provide a range of balance and strengthening exercises suitable for use across broad levels of function, that has been shown to improve balance and mobility in older people living at home expressing concerns about their balance [31].

Exercises will be selected based on the results from a physical assessment by the therapist at the first intervention visit. Although the functional levels are likely to vary between the carer and the care recipient, the intervention therapist will aim to select several common exercises (with variation in elements such as foot position, amplitude of movement, dual task to modify the specific difficulty of the exercise to the individual). In this way the carer/care recipient dyad will be able to have some common elements to share as they exercise together. The participants will be provided with an illustrated booklet with a description, a picture and a dosage of each exercise prescribed, and an exercise recording sheet for each month of the program. If an exercise weight is required for a strengthening exercise, this will be provided by the therapist. Depending on assessment findings, level of comorbidity, safety, and endurance, participants will be provided with between four and eight exercises (20–30mins including rests) as well as a walking program. The therapist will review the exercises at the home of the participants each month. Exercises will be modified or progressed as required.

Control groups

This study has two control groups, a social control group and a usual-care control group. The aim of the social control group is to control for the potentially beneficial effect of the social aspect of the intervention [23]. The social control group will receive a similar number and

duration of visits to the physical activity intervention. A research assistant (a trained social worker) will visit the participating dyads five times over a six month period and engage in a semi-structured discussion about topics that are of interest to the carer dyad, such as family, hobbies, holidays they have had, but not including any information or encouragement to participate in physical activity. The discussions will be maintained for an equivalent time period to the physical activity intervention, about 80 minutes for the first visit and 50 minutes for subsequent visits.

Assessments/Measures

The primary outcome for this study is the proportion of carers without depressive symptoms, measured as those scoring 4 or less on the 15 item Geriatric Depression Scale (GDS 15) [32]. Improvement in mean GDS 15 will also be compared across groups as a secondary outcome. Other secondary outcomes are carer and care recipient physical activity and function, carer burden and carer satisfaction, health service use for both carer and care recipient, and care recipient falls. Table 1 below shows the assessment measures for each member of the dyad at each time point.

The baseline assessment will be conducted in the participants' home by a trained research assistant. Carers and care recipients will complete a number of measures at baseline and these will be repeated after the intervention at 6 months and 12 months after the baseline assessment. At baseline, both the carer and the care recipient will complete the following:

- General demographic information including age, gender, country of birth, preferred language, veteran status, paid employment, health problems, medications, falls in the preceding 12 months, social activities, health and other service use for the preceding 12 months including amount and type of respite services utilised.
- The 15-item version of the GDS [33], a shortened form of the GDS 30, developed by Yesavage and colleagues [32] to assess symptoms of depression in older adults, focussing on the affective and cognitive aspects of depression. A cut off of 5/6 has satisfactory sensitivity and specificity [33].
- The Human Activity Profile (HAP) [34]. This questionnaire evaluates 94 activities, which are rated by the participant as 'still doing', 'have stopped doing', or 'never did'. The Adjusted Activity Score (AAS) will be reported, which is calculated by subtracting from the highest numbered activity still being done, the number of lower number activities listed as 'have stopped doing'.

- The Step Test, a dynamic test of standing balance [35]. The number of times the participant steps one foot fully on and then off a 7.5 cm block step in 15 seconds is recorded. Each leg is tested separately, and performance on the worst side will be used for data analysis.
- Functional Reach (FR) test is a test of dynamic standing balance. Participants stand against a wall with their right arm raised 90 degrees. They are asked to reach as far forwards as possible without overbalancing and the distance of additional reach is measured [36].
- The Sit-stand Test will be used to measure functional lower limb strength with participants asked to stand up and sit down from a standard chair without using their arms five times (five stand ups) [37].
- An eyes closed static stand test, the Clinical Test of Sensory Interaction of Balance (CTSIB) [38]. Participants are tested with feet together, and performance of standing still with eyes closed is timed up to 30 seconds.
- The Timed Up and Go (TUG) [39]. The TUG tests mobility, balance, and leg strength. Participants are timed standing up from a standard chair, walking three metres, turning, then returning to sit again. Participants are requested to walk at their usual speed with their usual gait aid for indoors walking. Use of a gait aid will be recorded and participants will be requested to use the same gait aid for all retests.

Additional assessment that will be completed with the care recipient will include:

- Modified Barthel Index (MBI) [40]. The MBI consists of ten self-care and mobility items. These are: feeding, bathing, personal grooming, dressing, bowels, bladder, toilet use, transfers (bed to chair and return), mobility on level surface, and stairs. The 100-point MBI with five response categories will be used [41].
- The Standardized Mini-Mental State Examination (SMMSE) [42] screening instrument for measuring cognitive impairment. Scores range from 0 to 30 with 30 indicating no cognitive impairment.

Additional assessments that will be completed by the carer include:

- The Zarit Carer Burden Interview (ZBI) [43] to evaluate carer burden. Questions explore commonly reported carer difficulties, including their health, psychological well-being, finances, social life, and the relationship between the carer and the care recipient.

- Carers' Assessment of Satisfaction Index (CASI) [44]. The CASI involves 30 different items which are associated with the person being cared-for (10 items), with the caregiver (12 items), or which relate to interpersonal dynamics (8 items).

Table 1 – Data collection measures for carer and care recipient at each time points

Carer	Care recipient	Baseline	6 month follow-up	12-month follow-up	Monthly for 12 months
Demographic information	Demographic information	√			
Health problems – medications, falls, health and other service use questionnaires	Health problems – medications, falls, health and other service use questionnaires	√	√	√	√
GDS 15	GDS-15	√	√	√	
Human Activity Profile (HAP)	Human Activity Profile (HAP)	√	√	√	
Timed Up and Go (TUG)	Timed Up and Go (TUG)	√	√	√	
5 x Sit to Stand	5 x Sit to Stand	√	√	√	
Static Stand with eyes closed	Static Stand with eyes closed	√	√	√	
Step Test	Step Test	√	√	√	
Functional Reach Test	Functional Reach Test	√	√	√	
-	Modified Barthel Index (MBI)	√	√	√	
-	Standardised MMSE	√	√	√	
Zarit Burden Interview (ZBI)	–	√	√	√	
CASI	–	√	√	√	

Carers will also be asked to maintain a diary throughout the 12 months of the study. They will be asked to record in this diary any adverse events (such as falls or hospital admissions),

changes in level of physical activity for either the carer or the care recipient and changes in medications. A research assistant will telephone carers each month to capture diary information recorded during the previous month. Publicly subsidised health service costs will also be collected through the Medicare and Pharmaceutical Benefits Scheme claims information databases, while health service resource use not captured through these databases for the carer and care recipient will be captured through the carer's diary and telephone follow-up.

Focus groups

Three groups of 5 dyads (30 participants in total) will be randomly selected from the intervention ('Otago-Plus' group) to participate in focus groups following their 12-month follow-up assessment. The aim of this component of the study is to consult with study participants about the feasibility, acceptability, and sustainability of the intervention. Participants will be asked to provide feedback on the intervention, including their preferences (likes and dislikes), barriers and enablers to participation, and their likelihood of continuing with the program once the research team have ceased contact.

Recruitment procedures

Interested participants will initially be screened by telephone by a research assistant trained in the use of the GDS 15 and in recognising cognitive impairment, to ensure eligibility. Because carers who have a GDS 15 score ≥ 5 are to be included in the study, they will be asked if they have sought advice from their general practitioner (GP) regarding their depressive symptoms, and if not, they will be encouraged to do so prior to participating in the study. The baseline assessment will be booked as soon as possible after the screening. Where there is an interval of four weeks or more between the screen and baseline, the GDS 15 will be readministered to ensure the carer is still eligible. Telephone interpreters will be used if required. After giving informed consent to participate, eligible carers and care recipients will undergo a detailed baseline assessment.

Ethical considerations

Participants' involvement in the trial will be voluntary and they will be informed that they can withdraw at any time, without any changes to their usual treatment. Written consent will be obtained. If the care recipient has a diagnosis of dementia or any other condition impacting on cognitive capacity and is unable to provide consent, their carer will be asked to provide this. Their information will be kept confidential and de-identified. However, if a participant expresses suicidal ideation throughout the study or shows any other signs of severe

depression, arrangements will be made for the participant to have a follow up review and risk assessment by a mental health clinician/old age psychiatrist. All records will be kept securely and for five years post publication according to ethics protocol.

After the final assessment, participants in both control groups will be invited to attend an education session on physical activity, that will include a presentation of the study findings and recommendations about physical activity for older Australians [45], as well as information about physical activity programs available to them in their local community.

Ethics approval was obtained through the Melbourne Health Human Research Ethics Committee on 21 February 2012 (HREC number 2012.041) and from the Grampians/Ballarat HREC on 4 August 2012 (HREC Reference Number: HREC/12/BHSSJOG/73).

Study governance

Apart from regular meetings of all investigators to monitor progress of the study, a study advisory committee has been formed to ensure that the perspectives of carers and older people are considered in the implementation of the study and that findings can be translated into clinical practice and government policy. This committee will meet at least once a year and consists of government policy officers, a representative from *beyondblue*: the national depression initiative (Australia), representatives of carer and older person peak bodies, as well as members of the project team.

Randomisation

The random numbers sequence will be generated and held by researchers from an external organisation, the Melbourne Epi Centre. The sequence will be generated through a computer generated list of random numbers using STATA12 (StataCorp, TX, USA) with an allocation ratio of 3:3:1 (intervention group: social control group: usual care control group). This allocation ratio will be employed to identify the smaller clinically important difference between the intervention group and social control group, compared to the comparison with the usual care control group. Random permuted blocks of 7, 14 and 21 will be utilised to allow for the allocation ratio used and the sequence will not be sighted by the study researchers.

After the completion of each baseline assessment a specified study researcher will email the unique participant identifier to the Melbourne EpiCentre. A specified staff member at the Melbourne EpiCentre will allocate the next available number from the random number sequence to the unique participant identifier and email the group allocated back to the

specified study researcher. The specified study researcher will then apply the intervention or control groups' processes, on the basis of the group allocation. All emails between the specified researcher and the external organisation will be kept at both ends, to allow for review at a later date.

Blinding

Assessors of the repeat assessment and telephone follow-up of diary data will be blinded to group allocation for the duration of the trial. There will be explicit instructions to participants and non-blinded research staff not to discuss which group participants are in. The researcher who receives the group allocation from the external researcher will inform participants of their group allocation and instruct them not to share this information with research staff involved in future assessments.

This trial commenced recruitment in April 2012 and is expected to be completed by 31 December 2015.

Data analysis

Statistical analysis

Based on data from Kerse et al [23], that identified a 30% reduction in the proportion of participants rated as depressed in the social control group of their program, for our study to detect a significant effect at 80% power and alpha of 0.05 (two-tailed), with 100% of the control sample (usual-care group) depressed at six months, and 70% in the social control group at six months, we will need 22 participants in each group. For the physical activity intervention to achieve a further 20% reduction in the number of depressed participants at six months relative to the social control group (ie, 50% of the intervention group depressed at six months), we require 93 participants in both the intervention and social control groups.

Allowing for 20% dropout, we will require 117 participants in these groups, and 28 participants in the usual care group. We will oversample for the control group in anticipation of a potentially higher dropout rate for participants not receiving any intervention, and will recruit in a 3:3:1 ratio—117 in intervention and social control groups, and 39 in the usual care group (total sample size $n = 273$).

All data will be analysed using intention to treat analysis. Logistic regression analysis will be used to analyse the effect of the intervention on the primary outcome variable, prevalence of no-depression, at six months and the secondary outcome variable, prevalence of no-depression at twelve months. Estimates (95% CIs) of the difference in mean GDS 15 between the groups at six and twelve months, will be derived using analysis of covariance. If the

distribution of GDS 15 is skewed it will be log transformed before analysis and the comparison between groups presented as the ratio of the geometric means. The effect of the intervention on secondary outcome measures will be evaluated using logistic regression for categorical variables and analysis of covariance for continuous measures. To analyse the effect of the intervention on events occurring throughout the year of follow-up negative binomial modelling will be used for recurrent events (eg, falls) and Poisson regression for single events (eg, permanent admission to residential care). To estimate the effects of potential baseline differences, analyses adjusted for baseline values will be undertaken within the models.

A sub-group analysis will be examined if a significant group*factor interaction effect is identified on the primary outcome. The subgroup factor to be considered will be the care recipient's level of cognitive impairment using a cut-off of 24 out of 30 on the SMMSE scale to demarcate these subgroups. Higher levels of depression and lower levels of physical health and wellbeing has been found amongst carers of people with dementia compared with other carers [46]. Caring for someone with dementia has also been found to negatively impact on healthy behaviours including exercise [47]. Outcomes of the intervention, therefore, may be influenced if the care recipient has cognitive impairment.

Focus group analysis

The focus groups will be audiotaped and transcribed. Two researchers will independently read through the transcripts and identify categories, using the research questions of acceptability, feasibility, and practicality of the intervention as the initial themes. The researchers will then meet and discuss their categories and seek agreement on how the data should be categorised, that is the content and level of each category. The themes and categories will then be entered into NVivo, a qualitative software package, as nodes and the transcripts coded according to the nodes. The percentage of data that can be accounted for using the initial nodes will be calculated and if it is necessary to add additional nodes to account for more of the data, this will be done independently and then discussed between the researchers until agreement is reached.

Economic evaluation

The economic evaluation will be an incremental cost effectiveness analysis that considers the efficacy of the intervention in reducing the proportion of carers who are depressed (GDS 15 $\geq$ 5) at the final follow-up assessment, compared to the control conditions. The evaluation will take place from the societal perspective and have a 12 month follow-up time-horizon. Direct

health costs of the dyad (visits to general practitioner, home nursing, respite), costs of providing the intervention (intervention, social control, usual care) and non-health costs (respite) and indirect costs (productivity losses incurred by carers having to take time off work to care) will be captured using the diary and interviews at assessment points. These costs will be used to construct the numerator in the incremental cost-effectiveness ratio. The difference between baseline and final assessments in depressed carers in the control groups will be subtracted from that of the intervention group to form the denominator. This estimate will be plotted on a cost-effectiveness plane and a 95% confidence ellipse will be constructed to demonstrate the uncertainty in the numerator and denominator of the incremental cost-effectiveness ratio. This will be converted into cost-effectiveness acceptability curves to identify how much stakeholders would need to be willing to pay in order for the intervention to be preferable over control conditions.

Discussion

There is evidence from quasi-experimental studies that physical activity can be an effective and safe intervention in reducing carer depression. This study aims to contribute to this knowledge by targeting the older carer and utilising an individualised home-based program for both the carer and care recipient. Inclusion of the care recipient may lead to increased motivation and enjoyment for both, which in turn may improve physical functioning in the care recipient, further reducing carer depression and burden. A clear gap in previous literature relates to lack of information on interventions in carer dyads, as well as the possible role that the social contact may reduce depression, rather than the physical activity itself. This current project aims to investigate these additional factors.

The inclusion of an economic evaluation means that the cost-effectiveness of this program can also be established, which has important implications for health and community services. If the intervention is both effective in terms of reducing depressive symptoms and cost effective, it has the potential to be rolled out broadly through community health services and carer support agencies as an early intervention for older carers who are displaying symptoms of depression. If the physical activity program proved to be acceptable to carers, feasible and practical, it could be introduced to carers by physiotherapists to alleviate their depressive symptoms which would improve their wellbeing and might enable them to continue caring for a longer period of time. Given the ageing population and the increased need for family carers in the future, this study has the potential to benefit the community as well as carers. If we can find ways of enabling carers to maintain their own health and wellbeing and continue

in the caring role, they will save the community the cost of caring for the care recipient as well as the potential cost of care for carers with poor health.

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