MONASH University

Effects of community based fitness program for people with chronic disease on health outcomes: Randomised Control Trial

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Monash University in 2018

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Abstract

Background

Engagement in regular physical activity is a critical component in preventing and managing chronic health conditions including cardiovascular disease, cancer, diabetes and obesity. Supervised exercise programs such as pulmonary or cardiac rehabilitation programs lasting four to six weeks can be effective ways for participants to commence or resume exercise in a safe and controlled environment. These programs have demonstrated effectiveness for improving clinical outcomes such as reduced risk of coronary artery disease and improved exercise tolerance in adults with chronic obstructive pulmonary disease. Adherence rates to ongoing exercise, however, decline or cease after the completion of the program, meaning clinical gains are lost, highlighting the need for effective maintenance strategies. There is limited evidence to suggest which interventions are the most clinically effective and cost-efficient in enhancing ongoing adherence to a prescribed program. The objective of this thesis was to investigate the effectiveness and cost-efficiency of gym-based versus home-based exercise with telephone follow up amongst adults with chronic conditions who had already completed a short-term exercise program supervised by a health professional. The final objective was to identify and compare participants' perceptions about their own motivation, capacity and opportunity to adhere to an allocated exercise program during either a gym-based or a home-based exercise program with telephone follow-up.

Method

This thesis commenced with (1) a systematic review and meta-analysis of literature to evaluate the effectiveness of follow-up approaches to sustain physical activity levels. A prospective randomised controlled trial (n=105) with 12 month follow-up was then conducted to (2) compare the clinical effectiveness and (3) cost efficiency of a home-based exercise program with telephone follow up compared to a gym-based follow up program amongst adults with chronic conditions who had already completed a short-term exercise program supervised by a health professional. The final study (4) was conducted on completion of the trial, and aimed to identify and compare participants' perceptions of participating in either intervention using qualitative design with thematic analysis.

Results

The review (1) found no difference in the proportion of participants who were fully adherent to an exercise program at 12 months between the centre-based follow-up and telephone follow-up interventions. The randomised controlled trial (2) found no significant difference between study groups in the primary outcome (Health Related Quality of Life as measured by the EQ-5D visual analogue scale) across the 12-month intervention period, although the gym group reported slightly fewer symptoms of depression over the 12-month period compared to the home group. The economic analysis (3) found the gym-based follow-up would cost an additional $491,572 AUD from the societal perspective to gain one quality adjusted life year compared to the telephone-based approach. The qualitative analysis, (4) found that improved social interaction in gym-based programs may contribute to adherence, however home based programs were perceived as more convenient and easily integrated into daily routines.

Conclusion

Similar long-term clinical outcomes and long-term exercise adherence were achieved with the gym-based versus home-based exercise with telephone follow up in the randomised controlled trial. Study (2) found

participation in gym-based group exercise may improve mental health outcomes slightly more, although was more costly (3) to implement. These additional costs are unlikely to be justified by differences in health outcomes attained. The qualitative study (4) found providing health coaching in parallel to exercise may improve self-efficacy and assist with removing many of the intrinsic and extrinsic barriers. Enablers for those in the gym-based group primarily revolved around improved social interaction whereas the home-based program was easily integrated into participants' daily routine as it eliminated transport and access barriers. Clinicians could justifiably employ either of these follow-up approaches in clinical practice. Further research conducted across multiple socioeconomic groups and with an additional no-intervention comparison group is warranted to further inform clinical decision-making in this area.

Keywords

Chronic Disease, Exercise, Adult, Economic Evaluation, Physical Therapy

General Declaration

This thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Signature 

Print name: Paul Jansons

Date 24/04/2018

Thesis including published works General Declaration

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes four original papers published in peer reviewed journals. The core theme of the thesis is to evaluate the clinical effectiveness and cost-efficiency of gym-based versus home-based exercise with telephone follow up amongst adults with chronic conditions that have completed a short-term exercise program supervised by a health professional. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the candidate, working within the Faculty of Medicine, Nursing and Health Sciences under the supervision of Professor Terry Haines and Associate Professor Lisa O'Brien.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

In the case of Chapters 1, 3, 4 and 5 my contribution to the work involved the following:

Thesis chapter	Publication title	Publication status*	Nature and extent (%) of students contribution	Co-author name(s) Nature and % of Co-author's contribution*	Co-author(s), Monash student Y/N*
1	Interventions to achieve ongoing exercise adherence for adults with chronic health conditions who have completed a supervised exercise program: Systematic review and meta-analysis	Published *Clinical Rehabilitation*	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication 85%.	Haines, T.P. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 5% O'Brien, L. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 10%	N N
3	Gym-based exercise and home-based exercise with telephone support have similar outcomes when used as maintenance programs in adults with chronic health conditions: a randomised trial	Published *Journal of Physiotherapy*	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication 80%.	Robins, L. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 5% O'Brien, L. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 5% Haines,T.P. contributed to the conception of the study, undertook data analysis,	Y N N

				assisted in the drafting of the manuscript 10%	
4	Gym-based exercise was more costly compared with home-based exercise with telephone support when used as maintenance programs in adults with chronic health conditions: Trial-based comparative cost effectiveness	Published *Journal of Physiotherapy*	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication 80%.	Robins, L. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 5% O'Brien, L. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 5% Haines,T.P. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 10%	Y N N
5	Barriers and enablers to ongoing exercise for people with chronic health conditions: participants' perspectives following a randomized controlled trial of two interventions	Published *Archives of Gerontology and Geriatrics*	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication 80%.	Robins, L. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 5% Haines,T.P. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 5%	Y N

				O'Brien, L. contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 10%	N

I have renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

Student signature: [redacted] **Date:** 24/04/2018

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the student and co-authors' contributions to this work.

Main Supervisor signature: [redacted] **Date:** 24/04/2018

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I wish to express my sincere thanks to Professor Terry Haines and Associate Professor Lisa O'Brien for their incredible supervision and support throughout my PhD candidature. The knowledge and skills you have taught me has been invaluable and will continue to serve me long into my career.

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A special mention to my family and friends: my father, sister and my baby boy Liam. Finally, I would like to dedicate this thesis to the two beautiful women in my life. My wife for her love and support throughout my candidature and her constant reminder of what is really important in life. And my mother who lost her life way too early during my PhD candidature. I would like to thank you for encouraging me to pursue this research and the importance of education.

Oral and poster presentations by candidate

Oral presentations

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2014). Effects of a community based fitness program for people with chronic disease on health outcomes: RCT. Paper presented at the Victorian Allied Health Research Conference 2014, Melbourne Convention Centre, Melbourne, Australia, 28 March 2014.

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2015). Engaging Older People in Service Delivery. Paper presented at the Victorian Allied Health Research Conference 2014, *Preventing Falls - the latest in research and community services: Carrington Health*, Melbourne, Australia, 17 November 2015.

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2017). Cost effectiveness of gym and home-based exercise programs adults with chronic conditions. Paper presented at the Victorian Allied Health Research Conference 2017, Melbourne Convention Centre, Melbourne, Australia, 31 March 2017. Award: Student Research higher Degree Symposium

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2017). Clinical effectiveness of a home-based exercise program with telephone follow up compared to a gym-based follow up program amongst adults with a variety of chronic conditions. Paper presented at the *Department of General Practice Academic Seminar Series* 2016, Monash University, Melbourne, Australia, 27 April 2017.

Poster presentations

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2016). Gym-based exercise and home-based exercise with telephone support have similar outcomes when used as maintenance programs in adults with chronic health conditions: a randomised trial. Poster presented at the Australian Disease Management Conference 2016, Melbourne Convention Centre, Melbourne, Australia, 20-21 October 2016. Award: Best poster presentation

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2017). Trial-based comparative cost effectiveness analysis of gym versus home-based exercise programs with telephone follow up for adults with chronic health conditions Poster presented at the *Monash Health Translation Precinct Research Week* 2017, Melbourne University, Clayton, Melbourne, Australia, 13 November 2017.

Awards received

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2016). Gym-based exercise and home-based exercise with telephone support have similar outcomes when used as maintenance programs in adults with chronic health conditions: a randomised trial. Poster presented at the Australian Disease Management Conference 2016, Melbourne Convention Centre, Melbourne, Australia, 20-21 October 2016. Award: Best poster presentation

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2017). Cost effectiveness of gym and home-based exercise programs adults with chronic conditions. Paper presented at the Victorian Allied Health Research Conference 2017, Melbourne Convention Centre, Melbourne, Australia, 31 March 2017. Award: Student Research higher Degree Symposium

List of publications

Publications by candidate incorporated into thesis

Published

Jansons, P., Haines T,P., O'Brien, L., (2016). Interventions to achieve ongoing exercise adherence for adults with chronic health conditions who have completed a supervised exercise program: Systematic review and meta-analysis. *Clinical Rehabilitation. 31(4) 465- 477.* doi: 0269215516653995.

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2017) Gym-based exercise and home-based exercise with telephone support have similar outcomes when used as maintenance programs in adults with chronic health conditions: a randomised trial. *J Physiother*. 2017. 63 (3)154–160. doi: 10.1016/j.jphys.2017.05.018

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2018) Gym-based exercise was more costly compared with home-based exercise with telephone support when used as maintenance programs in adults with chronic health conditions: Trial-based comparative cost effectiveness. *J Physiother*. 2018.64 (1) 48-54 doi: 10.1016/j.jphys.2017.11.010

Jansons, P., Robins, L., Haines., T. & O'Brien., L. (2018) Barriers and enablers to ongoing exercise for people with chronic health conditions: participants' perspectives following a randomized controlled trial of two interventions. *Achieves of gerontology and geriatrics.* 2018. 76 (1) 92-99 doi: org/10.1016/j.archger.2018.02.010

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1 Chapter 1-Introduction

1.1 Background

This thesis seeks to investigate the effectiveness and cost-efficiency of gym-based versus home-based exercise with telephone follow up amongst adults with chronic conditions who had already completed a short-term exercise program supervised by a health professional. This introductory chapter will commence with the provision of definitions of health conditions and outcome constructs central to this thesis. It will then progress to a discussion of how low levels of physical activity is thought to contribute to the development and progression of many forms of chronic disease. Next will be a discussion of how physical activity interventions can be used to attempt to mitigate and even reverse the progression of some chronic diseases.

From this point, this chapter will then focus its scope towards the delivery of physical activity programs for people with chronic disease in the Australian health care context. The role of programs provided through community health centres will then be described, followed by a discussion of the key challenges for service providers in how to help people with chronic disease maintain the physical activity levels and health gains made while people attended their programs. A systematic review examining the effectiveness of follow-up approaches to sustain physical activity levels in people with chronic disease who have recently attended a supervised exercise program will then be presented. This will lead into presentation of the research aims to be discussed in the remainder of this thesis.

1.2 Definition of terms

1.2.1 Chronic disease

Chronic disease refers to a range of chronic and complex health disease that may include cardiovascular disease, musculoskeletal disease, mental disorders, cancer, diabetes-mellitus, chronic respiratory disorders, asthma and chronic obstructive pulmonary disease. These diseases are often complex in nature, have multiple causes, are often long term, progressive, and rarely curable. (World Health Organisation, 2016) The 2014-15 Australian national survey reported that 50% of Australian adults currently have at least one chronic disease and 60% over the age of 65 years have 2 or more chronic diseases. It is estimated that 90% of death in Australia is attributed to one or more chronic diseases and the prevalence, morbidity, mortality health care costs exponentially increase with age. (Australian Institute of Health and Welfare, 2016)

1.2.2 Cardiovascular disease

Cardiovascular diseases affect the heart and blood vessels and include heart disease, heart failure, cardiomyopathy, congenital heart disease, peripheral vascular disease and stroke. (World Health Organisation, 2016) It is estimated that 4.2 million Australians currently have one or more cardiovascular diseases. This results in the highest percentage of allocated health care expenditure in Australia at 12% and a standardised death rate of 197 per 100, 000 population or 34% of all deaths. (Australian Institute of Health and Welfare, 2016)

1.2.3 Musculoskeletal disease (rheumatoid arthritis, osteoarthritis and osteoporosis)

Osteoarthritis is a disease affecting the degeneration of cartilage in the joints such as the neck, lower back, knees and hips. Rheumatoid arthritis is an autoimmune disease resulting in the immune system attacking the swelling and inflammation of the joint, connective tissue, blood vessels and organs around the body.

(World Health Organisation, 2016) Osteoporosis is a skeletal disorder characterised by low bone density and micro-architectural deterioration of bone tissue leading to bone fragility and an increase in bone fracture. (World Health Organisation, 2016) It is estimated that 3 million Australians, including 50 percent of adults over the age of 75, have at least one of these three musculoskeletal conditions. The percentage of total allocated health care expenditure of these three musculoskeletal diseases was estimated to be 9.2%. (Australian Institute of Health and Welfare, 2016)

1.2.4 Cancer

Cancer is a disease of the body's cells. Cancer is one of the most preventable and treatable chronic diseases and is directly related to modifiable risk factors such as smoking, obesity and physical inactivity. There are over 100 types of cancers which may include lung disease, prostate cancer, breast cancer, cervical cancer, leukaemia, Hodgkins and non-Hodgkins lymphoma and sarcoma. (World Health Organisation, 2016) It is estimated that over 330,000 Australian adults have at least one diagnosis of cancer, with prostate and colorectal the most common. The percentage of allocated health care expenditure of all cancers in Australia is estimated to be 5.8%. A diagnosis of any type of cancer is directly attributed to 29% of all Australian deaths. (Australian Institute of Health and Welfare, 2016)

1.2.5 Diabetes-mellitus

There are 3 types of diabetes. Type 1 is an auto-immune disease where the body's immune system attacks the insulin producing cells. Type 2 is associated with hereditary factors and lifestyle risk factors such as physical inactivity and poor diet. (World Health Organisation, 2016) Gestational diabetes occurs in 3-8 percent of Australian pregnancies and may increase the risk of developing type 2 diabetes later in life. (Australian Institute of Health and Welfare, 2016) It is estimated that 700,000 Australians have diabetes. This accounts for 1.6 % of the allocated health care expenditure and a standardised death rate of 16 per 100, 000 population. Additionally, diabetes is the leading direct cause of a number of secondary conditions such as heart disease, cerebrovascular disease and renal failure. (Australian Institute of Health and Welfare, 2016)

1.2.6 Chronic respiratory disorders (such as Asthma and chronic obstructive pulmonary disease)

Asthma is a chronic lung inflammatory disorder. Chronic obstructive pulmonary disease is a progressive condition that limits airflow in the lungs. (World Health Organisation, 2016) It is estimated that 2 million Australians have some form of asthma and 600,000 have been diagnosed with chronic obstructive pulmonary disease. Asthma and chronic obstructive pulmonary disease are estimated to consume 1.4 % and 2 % of the total allocated health expenditure in Australia respectively. (Australian Institute of Health and Welfare, 2016)

1.2.7 Health-related quality of life

Health-related quality of life is subjective and multidimensional, that encompasses physical health, psychological state and social interaction. (de Wit & Hajos, 2013) Self-reported questionnaires that measure these individual components include the 36 item Short Form health survey (SF-36) (Ware Jr & Sherbourne, 1992) and the European Quality of Life survey (EQ-5D). (Dolan & Roberts, 2002) Many of these measures, for example the SF-36 and EQ-5D, also have the benefit of being able to be converted to a utility measure used in economic evaluation studies. (Lane, 1987) The EQ-5D-3L questionnaire utility measure contains five multiple-choice questions. The five questions reflect mobility, personal care, usual activities, pain/discomfort and anxiety/depression. The respondent selects one of three ordinal statements to describe their health for each. In order to obtain an overall score, the Dolan utility calculator (Dolan & Roberts, 2002) is applied. A utility measure is determined where 0 represents death and 1 perfect health.

The EQ-5D-3L has been shown in the older population (i.e. over 65 years) to be sensitive to change and simple to administer with a high completion rate. (Holland, Smith, Harvey, Swift, & Lenaghan, 2004) Further discussion on the reliability and validity of the EQ-5D-3L will be presented in Chapter 2.

1.2.8 Mental disorders such as anxiety and depression

Depression and anxiety disorders are different in definition, however, are often entwined as people with depression often experience symptoms similar to those of an anxiety disorder. (Zigmond & Snaith, 1983) Anxiety is defined as an emotion that has components of tension, with recurrent worried or intrusive thoughts or concerns, and depression as experiencing feelings and thoughts such as lack of interest and pleasure in daily activity, feelings of worthless or recurrent thoughts of death or suicide. (World Health Organisation, 2016) It is estimated that 2.1 million Australians have been diagnosed with anxiety and/or depression. The total allocated health care expenditure that is directly related to anxiety and/or depression is estimated to be 7.5%. (Australian Institute of Health and Welfare, 2016) A commonly used tool that has been validated in the older adult population to detect and assess the severity of both anxiety and depression is the hospital anxiety and depression scale (HADS). (Zigmond & Snaith, 1983) Further discussion on the reliability and validity of the HADS will be presented in Chapter 2.

1.2.9 Social isolation

Social isolation has objective and subjective components. A commonly accepted definition is living without companionship, having low levels of social contact, little social support, feeling separate from others, being an outsider, isolated and suffering loneliness. (Hawthorne, 2006) A recent observational study of 1682 participants reported that 19% of Australian adults over the age of 65 years were considered socially isolated. (Beer et al., 2016) The Friendship Scale (Hawthorne, 2006) can be used to measure social isolation. Social isolation has been shown to lead to a number of chronic health conditions such as coronary heart disease (CHD), worse outcomes post-stroke, arthritis and poor self-rated health. (Beer et al., 2016) To date, there is limited data on Australian health care expenditure directly related on Social isolation. Further discussion on the reliability and validity of the Friendship Scale will be presented in Chapter 2.

1.2.10 Physical activity

The World Health Organization defines physically active as accumulating 150 minutes of moderate intensity physical activity of any type per week for adults over 18 years old. (World Health Organisation, 2016) The American college of Sports Medicine defines exercise as activity that is planned, structured and repetitive in any form in order to improve and individual physical fitness. (Moore, Durstine, & Painter, 2016) With technological advances and urbanisation that deter day-to-day incidental exercise, there is a greater emphasis on improving the proportion of the population's planned structured and repetitive exercise to meet the recommended required exercise dosage. (World Health Organisation, 2016) For the purpose of this thesis, the working definition of physical activity or exercise is physical activity or exercise that is planned, structured, repetitive and prescribed by a health professional.

The prevalence of physical inactivity (i.e. not reaching 150 minutes of moderate activity per week) in men and women aged 18 years is a global issue that varies significantly across the world. The World Health Organisation identified physical inactivity as one of nine global non-communicable disease targets in 2014, aiming for a 10% relative reduction in prevalence of insufficient physical activity by 2020. (World Health Organisation, 2016) The World Health Organisation in 2010 identified globally that 23% of adults aged 18 and over were insufficiently active in 2010 (men 20% and women 27%). The prevalence of physical inactivity was found to double in high income countries (range 31%-32%) such as, Australia, the regions of the Americas and Eastern Mediterranean compared with low-income countries, such as those in South-East Asia and Africa (range 15%-21%). The global prevalence of physical inactivity in people aged > 65 years is estimated to increase proportionally up to 55%. (World Health Organisation, 2016) In the Australian

context, the Australian Bureau of Statistics reported the prevalence of physical inactivity to be 44% in Australian adults over the age of 65 years. The prevalence increases in low socio demographic or disadvantaged populations with estimates of 76% of adults not meeting the current world health organisation definition of physical activity. (Australian Institute of Health and Welfare, 2016)

1.3 Burden of physical inactivity related to chronic disease in Australia

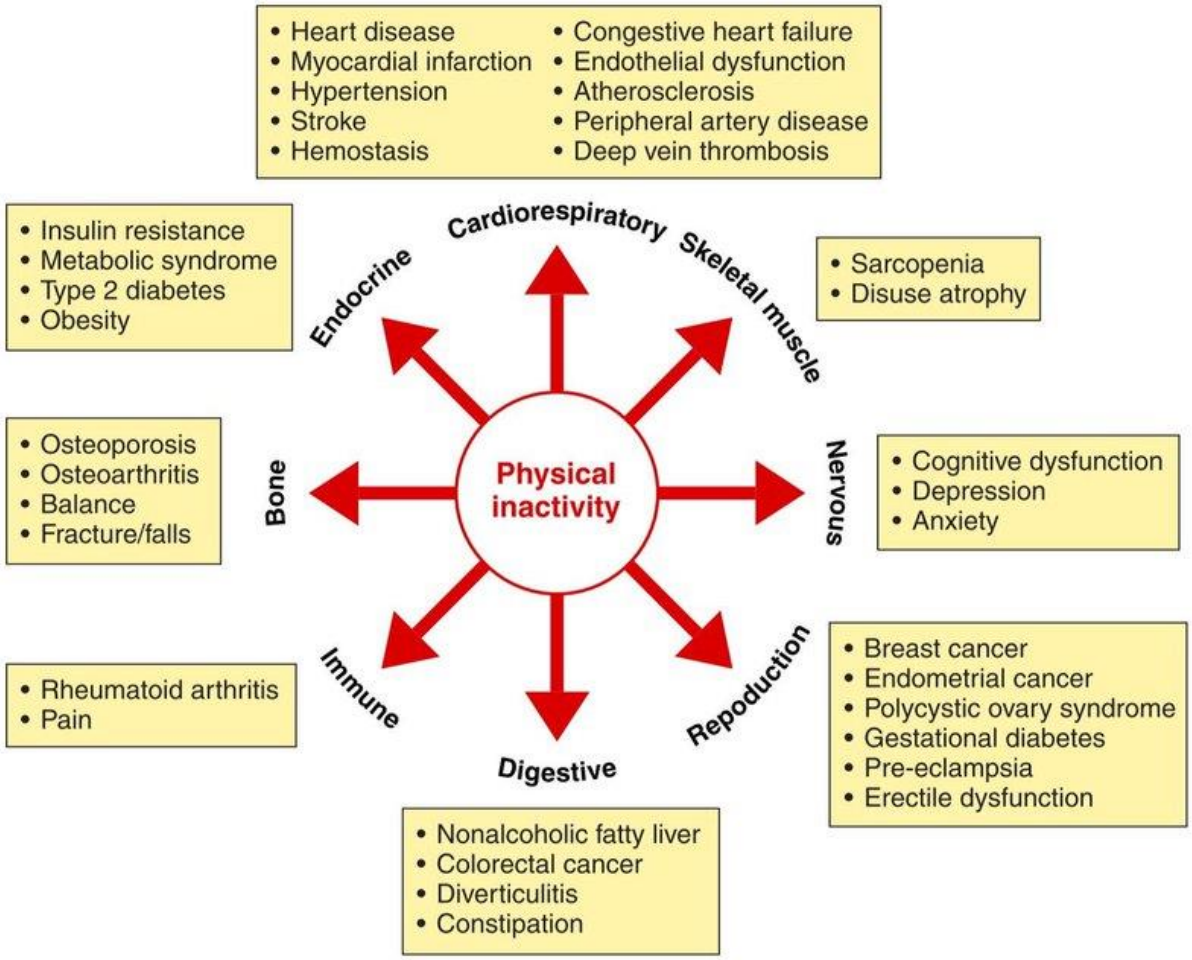

Figure 1-1 Lack of exercise is a major cause of chronic diseases. Comprehensive Physiology; reproduced with permission) (Source: Booth, F. W., Roberts, C. K., & Laye, M. J. 2012)

Figure 1.1 by Booth et al., 2017 illustrates that physical inactivity is recognised as an independent risk factor for up to 35 chronic diseases. (Booth, Roberts, Thyfault, Ruegsegger, & Toedebusch, 2017) In the Australian context, *The cost of illness attributed to physical inactivity in Australia study* report used the population attributable risk (PARS) approach to estimate the proportion of disease outcomes attributed to being inactive. Conservative estimates suggested that PARs for each disease were 18 per cent for cardiovascular disease, 16 per cent for stroke, 13 per cent for noninsulin-dependent diabetes mellitus, 19 per cent for colon cancer, 9 per cent for breast cancer and 10 per cent for depression. (Stephenson, Bauman, Armstrong, Smith, & Bellew, 2000)

The mortality rate for being inactive in Australia is thought to be as high as 18 percent. This contributes to the risk of 6,400 deaths per annum from cardiovascular disease, noninsulin-dependent diabetes mellitus and colon cancer. Other conditions such as breast cancer and stroke are thought to contribute up to 2200 deaths per year. It is estimated that 77,603 potential years of life lost because of inactivity in Australia.

(Stephenson, Bauman, & Armstrong, 2000) Physical inactivity causes a significant public health economic burden in terms of direct and indirect costs. Direct health care costs attributed to physical inactivity were estimated at $640 million per year in Australia. (Ding et al., 2016)

1.4 Potential benefits of exercise

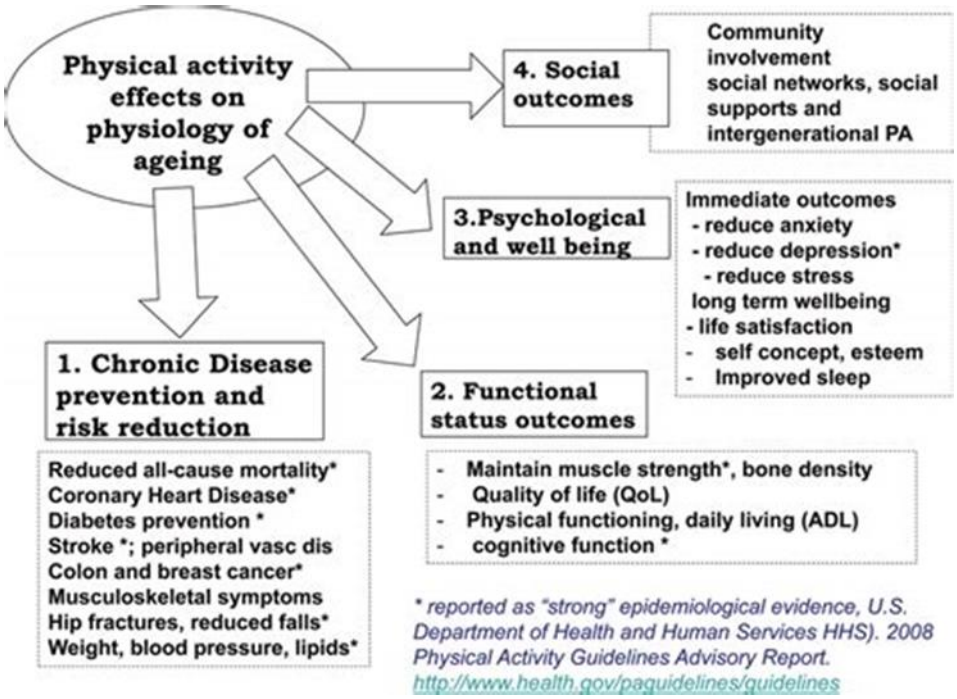

Figure 1-2 (Source: Bauman, A., Merom, D., Bull, F. C., Buchner, D. M., & Fiatarone Singh, M. A. (2016). Updating the evidence for physical activity: summative reviews of the epidemiological evidence, prevalence, and interventions to promote "Active Aging". *The Gerontologist*, *56*(Suppl_2), S268-S280: reproduced with permission)

Figure 1.2 by the U.S Department of Health and Human services presents a theoretical model that gives an overview of the benefits of physical activity on the physiological, psychological, functional and social effects of ageing.(Bauman, Merom, Bull, Buchner, & Fiatarone Singh, 2016)

The next section will present evidence of how physical activity interventions prescribed by a health professional can be used to attempt to mitigate and even reverse the progression of some chronic diseases. Evidence will be presented within the four key areas shown in Figure 1.2 to frame the following section: chronic disease prevention and risk reduction; functional status outcomes; psychological and well-being; and social outcomes.

1.4.1 Chronic disease prevention and risk reduction

Cardiovascular disease and exercise

A Cochrane review measuring the impact of 12-month centre-based cardiac rehabilitation programs (supervised by a health professional) for adults with ischaemic heart disease (N= 47 studies with 10,794 participants) found reduced overall cardiovascular mortality (risk ratio 0.87: 95% confidence interval [CI] 0.75 to 0.99) and hospital admission (risk ratio 0.69: 95% CI 0.51 to 0.93) compared to usual care. (Heran et al., 2011) Another Cochrane review (N= 33 trials; 4740 adults with heart failure) found a reduction in pooled mortality between centre-based rehabilitation (supervised by a health professional) in trials greater than one year compared no exercise control (risk ratio 0.88: 95% CI 0.75 to 1.02). Exercise also reduced heart failure specific hospitalisation (risk ratio 0.61: 95% CI 0.46 to 0.80) and improved disease specific

health related quality of life in the Minnesota Living with Heart Failure questionnaire (mean difference: -5.8 points; 95% CI -9.2 to -2.4). (Taylor et al., 2014)

Musculoskeletal disease (rheumatoid arthritis, osteoarthritis and osteoporosis) and exercise

A Cochrane review of 10 studies of 549 participants with mild to moderate symptomatic hip osteoarthritis found centre-based exercise programs (supervised by a health professional that included strengthening, aerobic and balance components) reduced pain (standardised mean difference of 8 points on a 100 point scale; 95% CI 4 to 11 points) and improved physical function (standardised mean difference -0.38: 95% CI -0.54 to -0.05) compared to no treatment control. (Fransen, McConnell, Hernandez-Molina, & Reichenbach, 2014)

Cancer and exercise

A Cochrane review of 32 studies involving 2626 women with breast cancer found that aerobic or resistance exercise interventions (either centre or home, supervised or non-supervised by a health professional) improved cardiorespiratory fitness (standardised mean difference 0.42: 95% CI 0.25 to 0.5) compared to non-exercise groups. Non-statistical improvements included self-reported fatigue and reduction in weight. (Furmaniak, Menig, & Markes, 2016) Another Cochrane review of three trials with 178 participants with lung cancer found an exercise program improved the six-minute walk distance compared to the control group (mean difference 50.4 metres: 95% CI 15.4 to 85.2). (Cavalheri, Tahirah, Nonoyama, Jenkins, & Hill, 2014)

Diabetes-mellitus and exercise

A Cochrane review of 14 trials of 377 participants with type 2 diabetes improved glycated haemoglobin levels (standardised mean difference 0.6%: 95% CI -0.0 to -0.3) by participating in exercise interventions (either centre or home, supervised or non-supervised by a health professional) ranging 8 weeks to 12 months compared to no exercise control. A reduction in visceral adipose tissue (standardised mean difference -45 cm: 95% CI -63.8 to -27.3) was also found in this review. (Thomas, Elliott, & Naughton, 2006)

Chronic respiratory disorders (asthma and chronic obstructive pulmonary disease) and exercise

A Cochrane review of 12 studies of 425 participants with chronic obstructive pulmonary disease found that upper limb training (endurance or resistance) improved feelings of dyspnea (mean difference 0.37: 95% CI 0.02 to .72) compared to either no training or sham training. Other improvements included unsupported endurance upper limb capacity (standardised mean difference 0.66: 95% CI 0.19 to 1.13). (Kathiresan, Jeyaraman, & Jaganathan, 2010) Another Cochrane review of five studies of 176 participants with chronic obstructive pulmonary disease found that water based exercise training improved the six minute walk distance (mean difference 62 metres: 95% CI 44 to 80 metres) and the incremental shuttle walk distance (mean difference 50 metres; 95% CI 20 to 80 metres) compared to control. (McNamara, McKeough, McKenzie, & Alison, 2010)

1.4.2 Functional status outcomes

Quality of life and exercise

A Cochrane review of 56 trials with 4826 adults diagnosed with either breast, prostate, gynaecologic and hematologic cancer found exercise interventions (either centre or home, supervised or non-supervised by a health professional) improved health related quality of life (standardised mean difference 0.33: 95% CI 0.12 to 0.55) from baseline to 12 weeks compared to a no exercise control. (Mishra et al., 2012)

Another Cochrane review of five studies of 176 participants with chronic obstructive pulmonary disease found that water based exercise training improved measures of health related quality of life (standardised mean difference -0.97, 95% CI -0.37 to -1.57). (McNamara, McKeough, McKenzie, & Alison, 2010)

1.4.3 Psychological and well-being

Anxiety/ depression and exercise

A Cochrane review of 35 trials of 2326 adult participants diagnosed with depression found exercise (either centre or home, supervised or non-supervised by a health professional) improved the symptoms of depression (pooled standardised mean difference -0.62: 95% CI -0.81 to -0.42). (Cooney, Dwan, & Mead, 2014)

1.4.4 Social outcomes

Social isolation and exercise

A mixed method review of 17 articles found the effect of 24 week centre-based (supervised by a health professional) on social isolation (pooled estimate 0.41:95% CI 0.08 to 0.75). Narrative synthesis outlined that older adults participating in group exercise programs improved social isolation, social network and their physical health. However, these results were not maintained long term. (Robins, Jansons, & Haines, 2016)

1.5 Limitations and potential risks of supervised physical activity programs

There is evidence that exercise adherence declines after supervised programs are completed, with many people ceasing altogether. A randomised controlled trial with 109 COPD participants found that approximately 50% of older adults ceased exercise within 9 months of completing a supervised exercise program.(Brooks, Krip, Mangovski-Alzamora, & Goldstein, 2002) Unfortunately, the benefits of exercise are rapidly lost when exercise is ceased, highlighting the need to promote ongoing participation. Out of 247 trials reported in section 1.4.1, 1.4.2, 1.4.3 and 1.4.4, only 32 trials reported adverse events. Common adverse events reported were muscle fatigue, tiredness and soreness. No trials reported falls, significant injury or death. (Cooney et al., 2014; Fransen et al., 2014; Heran et al., 2011; McNamara et al., 2010; Mishra et al., 2012; Robins et al., 2016; Taylor et al., 2014; Thomas et al., 2006) No trials provided data on costs.

1.6 Current provision of physical activity interventions to manage chronic disease in Victoria, Australia

Health care in Australia is divided into acute, subacute private or government (public) operated hospitals. (Australian Institute of Health and Welfare, 2016) Within the public system, hospitals are traditionally supported by community health services to assist with the transition of clients back to independent living. Other roles of community health services include health promotion, disease prevention and management to improve the health and wellbeing of individuals in the community. These services often include a range of multi-disciplinary services to support the throughput of clients from acute and sub-acute hospitals and provide a restorative and prevention role that may be staffed by dental, nursing and allied health. (Sibthorpe & Gardner, 2007)

An audit and gap analysis conducted by the Victorian Department of Health and Human Services was undertaken between November 2015 and February 2016 to examine the availability, variety and accessibility of physical activity opportunities for older Victorians over the 55 years of age. Of the total of 4,469 physical activity opportunities, the majority 2,741 were structured physical activities provided by

neighbourhood houses, community centres and fitness or leisure centres. These structured exercise programs commonly included either a mixed diagnostic or disease specific admission criteria were grouped into either walking, strength training, tai chi/qi gong, group exercise (land), hydrotherapy/water exercise and yoga/Pilates. The majority of these centre-based exercise programs were land-based group exercise, supervised by qualified instructors (with training to lead a particular physical activity) and considered short term (up to 10 weeks). (De Silva, Nolan, Smith, & Menzies, 2016)

Community health services in Victoria are traditionally flexible with their models of service to meet the needs of individuals living in their catchment area. (Sibthorpe & Gardner, 2007) Key community health stakeholders have the role of operationalising the delivery of the best evidence based practice, in terms of exercise interventions prescribed by a health professional, in an attempt to mitigate and even reverse the progression of chronic diseases. Community health services may focus on disease-specific diagnostic rehabilitation groups such as cardiac and pulmonary rehabilitation depending on the volume of referrals.(Sibthorpe & Gardner, 2007) Another less common model provided by community health services is mixed population rehabilitation groups. These are potentially useful in regional and rural areas where throughput of cases within a specific diagnostic grouping is insufficient to justify a disease specific rehabilitation program, for example, pulmonary rehabilitation. (De Silva et al., 2016) Commonly these exercise programs are short term, ie 4 to 6 weeks, due to public health system funding constraints. (Sibthorpe & Gardner, 2007)

Given the loss of benefit with non-adherence to ongoing exercise, a question that must be raised is how can ongoing participation in exercise programs best be supported following the completion of a supervised exercise program in the Australian context. There are a number of possible interventions for enhancing adherence to exercise after a supervised exercise program. These include telephone follow-up, supervised community gymnasium integration and home exercise program with no follow up. The relative effectiveness of these interventions is now considered through a systematic literature review and meta-analysis.

1.7 Preface to systematic review

The following text is adapted from an article published in 2016. The article citation is Jansons, P., Haines T,P., O'Brien, L., (2016). Interventions to achieve ongoing exercise adherence for adults with chronic health conditions who have completed a supervised exercise program: Systematic review and meta-analysis. *Clinical Rehabilitation. 31(4) 465- 477.* doi: 0269215516653995.

This systematic review focuses on the outcome of adherence to an exercise program. This is traditionally a process evaluation outcome measure in studies of exercise programs. In this thesis, I am particularly interested in understanding the differences between gym-based versus home-based exercise with telephone follow up amongst adults with chronic conditions who had already completed a short-term exercise program supervised by a health professional. It is therefore important for me to first understand the likely impact of these differences in follow up approaches on the key mechanism (Participation in exercise) through which these follow up approaches may improve the health and well-being for participants with chronic disease. I therefore undertook this systematic review prior to examining the comparative efficacy or effectiveness and cost effectiveness of gym-based versus home-based exercise with telephone follow up.

Declaration for Thesis Chapter 1

Jansons, P., Haines T,P., O'Brien, L., (2016). Interventions to achieve ongoing exercise adherence for adults with chronic health conditions who have completed a supervised exercise program: Systematic review and meta-analysis. *Clinical Rehabilitation. 31(4) 465- 477.* doi: 0269215516653995.

Monash University

Declaration by candidate

In the case of Chapter 1, the nature and extent of my contribution to the work was the following:

Nature of contribution	Extent of contribution (%)
Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication.	85%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	Nature of contribution	Extent of contribution (%) for student co-authors only
Terry Haines	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	5%
Lisa O'Brien	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript 10%	10%

Candidate's Signature	[redacted]	**Date** 24/04/18

Declaration by co-authors

The undersigned hereby certify that:

(1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(4) there are no other authors of the publication according to these criteria;
(5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	Allied Health Research Unit, Kingston Centre, Warrigal Rd, Cheltenham 3192

Signature 1	[redacted] Lisa O'Brien	**Date** 24/04/18
Signature 2	Terry Haines	24/04/18

1.8 Systematic Review

1.8.1 Abstract

Background

There are several possible interventions that may promote ongoing exercise participation and adherence to prescribed exercise programs. These may include telephone follow-up, supervised community gymnasium integration, home exercise programs, activity monitors and web based activity diaries. There is, however, limited evidence to suggest which interventions are the most effective in enhancing ongoing adherence to a prescribed program.

Objective

To determine which exercise interventions are most effective for achieving ongoing exercise adherence in adults with chronic health conditions who had already completed a supervised short-term program.

Method

Search of MEDLINE (Ovid Medline 1946 to April 8th, 2016), EMBASE (1980 to April 8th, 2016), CINAHL (1982-April 8th 2016) and the Cochrane Central Register of Controlled Trials was conducted. The chronic health conditions search terms as per the Chronic Disease and Participation in Work AIHW Report, 2008. Included were randomised (or quasi-randomised) trials and observational studies evaluating interventions that aimed to improve exercise adherence in adults with chronic health conditions that had completed a supervised exercise program. Random-effects meta-analyses and random-effects logistic meta-regression were used to examine relationships between exercise adherence strategy and adherence.

Results

Eleven studies were included with a total of 1231 participants with Chronic Obstructive Pulmonary Disease, Diabetes, Cardiovascular disease or Osteoarthritis. Methods used for maintaining adherence were categorized post hoc as: centre based programs; home exercise programs with telephone follow-up; home exercise programs with no follow-up; and weaning programs that transitioned patients to an independent, off-site exercise program.

There was no difference in the proportion of participants who were fully adherent to an exercise program 12 months between the centre-based follow-up (pooled proportion fully adherent=0.34) and home based exercise program with telephone follow-up (pooled proportion fully adherent=0.30, difference p-value=0.75).

Conclusion

Interventions such as centre-based exercise programs or home exercise programs (with or without telephone follow-up) do not differentially impact exercise adherence for people who have completed a short-term supervised program.

Keywords

Systematic review, Chronic Disease, Adults, Exercise, Adherence

1.8.2 Introduction

Ongoing adherence to physical activity programs is a critical component in preventing and managing chronic health conditions including diabetes, cardiovascular disease, chronic neurological conditions, cancer and obesity.(*Australian Bureau of Statistics. Physical activity in Australia: a snapshot, 2004-05*, 2011) Structured programs involving at least 4-6 weeks of exercise under expert supervision have been shown to improve health outcomes such as quality of life, anxiety and depression, and functional exercise capacity.(Cambach, Wagenaar, Koelman, van Keimpema, & Kemper, 1999; Castaneda et al., 2002; Griffiths et al., 2000a; Maiorana, O'Driscoll, Goodman, Taylor, & Green, 2002; Singh, Smith, Hyland, & Morgan, 1998) These short-term programs focus on the safe adoption of exercise, however long-term maintenance of regular exercise behaviour may require a different approach.(Hughes et al., 2010)

There is evidence that exercise adherence declines after the programs are completed,(Brooks et al., 2002) with many people cease altogether. One study found that approximately 50% of older adults ceased exercise within 9 months of completing a supervised exercise program.(Brooks et al., 2002) Unfortunately, the benefits of exercise can be rapidly lost if exercise is ceased, (Sherrington, Tiedemann, Fairhall, Close, & Lord, 2011) highlighting the need to promote ongoing participation. There are several possible interventions that may promote ongoing exercise participation and adherence to prescribed exercise programs. These may include telephone follow-up, supervised community gymnasium integration, home exercise programs, activity monitors and web based activity diaries.(Marla K Beauchamp, Evans, Janaudis-Ferreira, Goldstein, & Brooks, 2013; Dunstan et al., 2006)

Elements of an ongoing exercise adherence intervention may include self-efficacy enhancement (to allow participants to take ownership of their own exercise behaviour),(Teychenne et al., 2015) relapse prevention, and learning how to independently and safely adapt the exercise programs when there is an exacerbation of the chronic condition. (Brooks et al., 2002) There is, however, limited evidence to suggest which interventions are the most effective in enhancing ongoing adherence to a prescribed program.

1.8.3 Objective of this review

The aim of this review was to determine the most effective intervention for achieving ongoing exercise adherence in adults with chronic health following completion of a supervised exercise program. Specific objectives were to estimate and compare pooled full and partial adherence levels to prescribed exercise programs for different types interventions aimed at increasing adherence.

1.8.4 Methods

Search strategy of this review

An expert university Librarian conducted searches of the following electronic databases to April 8th, 2016 inclusive, EMBASE (1980 to April 8th , 2016), Medline (Ovid Medline 1946 to Present), Cochrane Central Register of Controlled Trials and Cinahl (1982 to April 8th 2016). The project investigators constructed a list of search terms under the headings “Participant”, “Participant[a”] , “Intervention”, “Intervention[b”], and “Outcome” (Table 1.1: Search terms). Headings were combined using the Boolean operator “OR” and then the “Participant” “Participant[a”] yield and the “Intervention”, “Intervention [b”] yield were combined using the Boolean operator “AND”. The Participants yield, Interventions yield, and the Outcome heading were then combined using the Boolean operator “AND”. An example search strategy is shown in Appendix. A– Full search strategy for Medline.

These chronic health conditions search terms were selected using the Australian Institute of Health and Welfare Focus Conditions, excluding chronic kidney disease and oral disease (as per the Chronic Disease and Participation in Work AIHW Report, 2009 (Welfare, 2009).

Participant words[a]	Participant word	Intervention words	Intervention word[b]	Outcome words
*Heart disease Stroke Cerebrovascular accident CVA Type 2 diabetes Non-insulin dependent diabetes Musculoskeletal Neurological Osteoarthritis Osteoporosis Depression Arthritis Asthma Chronic obstructive airways disease Chronic obstructive pulmonary disease Pre-existing disease Chronic disease Co-morbidity Comorbidity	Community Health Community-Based Community-Dwelling Adult	Phone Tele-health Telephone calls Follow up Advice Management-strategies Reward Punishment Verbal-Instructions Written-Instructions Action Plan Goal Setting Coping Plan Positive-Reinforcement Self-efficacy Barriers Education Reminder Counselling Information Partnership Co-operation Motivational-Interviewing Health Coaching Support Partnership Co-operation	Physical activity Physical intervention Exercise	Adherence Uptake Occasions of Service Dose Compliance Patient Contact

Table 1-1 Search terms

*These chronic health conditions search terms were selected using the Australian Institute of Health and Welfare Focus Conditions, excluding chronic kidney disease and oral disease (as per the Chronic Disease and Participation in Work AIHW Report, 2009. (Australian Institute of Health and Welfare 2009)

Study Selection

Inclusion criteria of this review

The inclusion criteria were: randomized, quasi-randomized, or observational studies published in English with adults over 18 years old with one or more chronic health conditions who had already completed a

supervised exercise program. The studies also needed to provide a measure of ongoing exercise adherence, such as the proportion of participants that fully completed or partially completed a prescribed number of exercise sessions.

Assessment of risk bias

Two review authors independently assessed the methodological quality of the included studies using a modified Cochrane Collaboration tool for assessing risk of bias. (Higgins, 2003) The random sequence generation domain was modified to selection bias domain and allocation concealment was deleted due to the small number of randomised controlled trials within the study. Any disagreement was discussed amongst all review authors to achieve consensus.

Decision rules were specified to the assessor to assign a 'high risk', 'low risk' or 'unclear' specified to each criteria (Table 1.2: Assessment of risk of bias). An additional risk of bias domain named study participant selection was used to describe potential bias in each studies inclusion and exclusion criteria.

Table 1-2 Assessment of risk bias

Study/Year	Selection bias	Blinding of Participants and Personnel	Blinding of Outcome Assessor	Incomplete Outcome Data	Selective Reporting	Other Source of bias
Beauchamp et al (2013)	Unclear	High Risk	High Risk	Unclear	Unclear	Low Risk
Berry et al (2003)	Low Risk	High Risk	Low Risk	Unclear	Unclear	Low Risk
Brooks et al (2002)	Low Risk	High Risk	Unclear	High Risk	Unclear	Low Risk
Carlson et al (2000)	Unclear	High risk	High risk	Low Risk	Unclear	Low Risk
Cochram et al (2006)	Unclear	High Risk	Unclear	High Risk	Unclear	Low Risk
Dunstan et al (2010)	Unclear	High Risk	Unclear	Low Risk	Unclear	Low Risk
Ries et al (2003)	Unclear	High Risk	Unclear	Low Risk	Unclear	Low Risk
Ringback et al (2010)	Unclear	High Risk	Unclear	Low Risk	Unclear	Low Risk
Roessler et al (2009)	Unclear	High Risk	Unclear	Unclear	High Risk	Low Risk
Spencer et al (2009)	Low Risk	High Risk	High Risk	Low Risk	Unclear	Low Risk
Teychenne (2015)	Low Risk	High Risk	Low Risk	Low Risk	Unclear	Low Risk

1.8.5 Data analysis

Two independent reviewers screened the titles and abstract of all papers after the completion of the search strategy against the inclusion and exclusion criteria. All identified papers were then screened in full text against the inclusion and exclusion criteria and then data were extracted. A third reviewer was consulted to resolve any difference in opinion.

Data on the amount of support provided by health professional/s or exercise professional/s to deliver each exercise intervention were extracted. Other components included goal exercise session attendance, duration of intervention in weeks and the health professional administering intervention (Table 1.3 – Components of health professional/exercise professional support).

Table 1-3 Components of health professional/exercise professional support

	Health professional administering intervention [a]	Public/private health patient recruitment [b]	Duration program in weeks	Goal exercise sessions [c]	Goal session length in minutes	Number of Telephone calls per month	Total number of Telephone calls	Number of centre support per month	Total number of centre support
Beuchamp et al. (2013)	FI	✓	52	2	60	.	.	8	104
Berry et al (2003)	PT	✓	65	3	60		.	12	144
Brooks et al (2002) A Centre	PT	✓	52	.25	120	.	.	1	12
Brooks et al. (2002) A. Telephone	PT	✓	52	3	60	1	12	.	.
Carlson et al. (2000) Weaning strategy	Unknown	✓	25	.	.	.	.	.	.
Cockram et al. (2006) A Centre	PT	✓	40	1	60	.	.	4	40
Cockram et al. (2006) A Telephone	PT	✓	52	3	20	?	?	.	.
Dunstan et al. (2006) A Centre	EP	X	52	2	60			1	12

Dunstan et al. (2006) B Telephone	EP	X	52	2	60	1	12	.	.
Ries et al. (2002) Centre	PT	✓	52	.25	180	.	.	1	12
Ringbaek et al. (2009) Centre	Unknown	✓	52	.	.	.	.	4	49
Roessler et al. (2009) HEP no telephone	PT	✓	52	3	60	.	.	.	.
Spencer et al. (2010) A Centre	PT	✓	52	1	60	.	.	4	52
Spencer et al. (2010) A HEP no telephone	PT	✓	52	4	60	.	.	.	.
Teychenne (2015) A. EI Centre	FI	X	52	3	60			8	
Teychenne (2015) B. Centre		X	52	3	60			8	

[a] The qualifications of the health professional delivering the exercise adherence intervention

[b] ✓ the participant was recruited through public/private health care; X: The participant was not recruited through public/private health care

[c] The amount of times per week each participant was instructed to complete the exercise adherence intervention

All data was extracted in Australia (2015)

PT=Physiotherapist, EP= Exercise Physiologist, FI= Fitness Instructor, EI=Enhanced behavioural intervention

Where possible we extracted data under the heading of “full adherence” which was defined as participant completion of 100 percent of the prescribed number of exercise sessions. In doing this, we also extracted what the frequency of prescribed sessions per week was and the number of weeks of prescribed program duration. “Partial adherence” was defined as completing a threshold proportion of the prescribed number of exercise sessions. In doing this, we additionally extracted the threshold proportion as described by the authors.

For example, Ries et al (2013)(Ries, Kaplan, Myers, & Prewitt, 2003) reported that 74% of participants completed a centre based exercise intervention were “partially adherent” to (ie. completed 67% of) a program that was prescribed to be undertaken once per month for 52 weeks. For this we extracted 74% as the “partial adherence value”, 67% as the “threshold” value, 0.25 as the “frequency per week” value and 52 as the “duration” value.

Data on participant adherence was extracted separately where a randomised controlled trial had two exercise adherence interventions. (Dunstan et al., 2006; Spencer, Alison, & McKeough, 2010; Teychenne et al., 2015) This effectively treated each study arm as a cohort study. Data was also extracted separately when an observational study provided two exercise adherence interventions.(Cockram, Cecins, & Jenkins, 2006) (Refer to Table 1.4: Summary of included trials (adherence data). Raw adherence data was requested from the authors of five studies to supplement summative data presented, (M. K. Beauchamp, Francella, Romano, Goldstein, & Brooks, 2013; Michael J Berry et al., 2003; Brooks et al., 2002; Ries et al., 2003; Roessler & Ibsen, 2009) however no responses were received.

Table 1-4 Summary of included trials (adherence data)

							"Fully adherent" to an exercise Program			"Partially adherent" to an exercise program			
	Exercise adherence intervention	**Control group**	**Methods to gather exercise adherence data**	**Duration in weeks**	**Number of participants in Intervention**	**Number of participants excluding drop-outs**	**Number of participants "fully adherent"**	**Percent of total number participants "fully adherent"**	**Percent of participants excluding drop-outs "fully adherent"**	**Number of participants in intervention**	**Reported threshold of participant adherence**	**Percent of total number participants "partially adherent"**	**Percent of participants excluding drop-outs "partially adherent"**
Beuchamp et al. (2013)	Gym program at community centre (aerobic & resistance)		AT gym recorded	52	29	23	16	55.51%	70.00%	.	.	.	.
Berry et al. (2003)	Gym program at university (aerobic & resistance)	No IV	AT gym recorded	65	64	62	32	50.38%	52.00%	.	.	.	.
Brooks et al. (2002) A Centre	Gym program at outpatient Centre (aerobic & resistance)	.	AT centre recorded	52	36	18	7	30.33%	39.00%	.	.	.	.
Brooks et al. (2002) A Telephone	Telephone HEP (aerobic & resistance)	.	EAQ	52	37	18	.	.	.	9	50.00%	24.3%	50.00%
Carlson et al. (2000)	Centre based weaning with HEP	Centre based TP	AT centre recorded	25	38	.	.	.	.	.	.	.	.

Cockram et al. (2006) A Centre	Gym program at outpatient centre (aerobic & resistance)	.	AT gym recorded	40	21	14	9	44.47%	66.67%	.	.	.	.
Cockram et al. (2006) A Telephone	Telephone HEP (walking program)	.	log book	52	21	7		30.33%	39.00%	.	.	.	.
Dunstan et al. (2006) A Centre	Gym program at local community gym (resistance training only)	.	log book	52	28	26	18	62.40%	68.00%	.	.	.	.
Dunstan et al. (2006) B Telephone	Telephone HEP (resistance training only)	.	log book	52	29	28	19	60.00%	67.00%	.	.	.	.
Ries et al. (2002) Centre	Gym program at outpatient centre (aerobic & resistance)	No IV	AT centre recorded	52	87	74	.	.	.	65	66.67%	74.71%	87.83%
Ringbaek et al. (2009) Centre	Gym program at outpatient centre (aerobic & resistance)	No IV	AT centre recorded	52	96	55	38	68.63%	75.50%	.	.	.	.
Roessler et al. (2009)	HEP no follow up (ex prescription unknown)	.	log book	52	811	445		.	.	228	80.00%	28.11%	52.24%

HEP no telephone												
Spencer et al. (2010) A Centre	Gym program at outpatient centre (aerobic & resistance)	log book	52	31	24	.	.	.	22	80.00%	70.97%%	91.67%
Spencer et al. (2010) A. HEP no telephone	HEP no follow up (aerobic & resistance)	log book	52	31	24	.	.	.	18	30.00%	58.84%	75.83%
Teychenne (2015) A. EI Centre	Gym program at local community gym (resistance training only)	AT centre recorded	52	162	139	32	19.75%	24.80%	.	.	.	.
Teychenne (2015) B. Centre	Gym program at local community gym (resistance training only including enhanced behavioural component)	AT centre recorded	52	156	136	15	9.12%	11.03%	.	.	.	.

All data extracted in Melbourne, Australia (2016)

HEP=Home exercise program, ex=exercise, Attendance =AT, Exercise adherence questionnaire = EAQ, Intervention =IV, Traditional Program=TP

EI=Enhanced behavioural intervention

A random effects meta-analysis was conducted using pooled data on participants that were "fully adherent" and "partially adherent" to an exercise adherence intervention. A primary analysis and sensitivity analysis were performed. The primary analysis utilised the number of participants who were classified as adherent as the numerator and the total number of participants in that group at baseline as the denominator. A sensitivity meta-analysis was also conducted which utilised the number of participants who completed the follow-up (minus drop outs) as the denominator**.**

Some studies reported the total proportion of possible goal exercise sessions completed. To calculate the 95% CI for these proportions, we had to take account of the clustering of session completion within participant. We therefore calculated variances based on session completion and inflated these using a design effect approach proposed by White et al (2005) (I. R. White & Thomas, 2005) for adjustment of clustering effect of studies. An intra-cluster correlation coefficient of .265 was used as this was the intra-cluster correlation calculated from a participant-level dataset generated by the investigators from a randomised controlled trial of telephone versus centre-based follow-up strategies amongst people with chronic disease conducted in Melbourne, Australia. The Australian New Zealand Clinical Trials Register: ACTRN: ACTRN12610001035011. The method and formulae used to calculate effect size estimates are reported in Lee et al (2014). (Lee, Pritchard, McDermott, & Haines, 2014)

Variances of the proportions adherent were also transformed using the Agresti-Coull Interval approach to obtain the confidence intervals that did not include values greater than 1 or less than 0. (Agresti & Coull, 1998) The between-study heterogeneity was measured with the I squared statistic. The DerSimonian-Laird random effects model was then utilised to pool the transformed proportion. Random effects meta-analysis plots were then created for "full adherence" and "partial adherence" methods.

A random effects meta-regression was conducted to examine the association between each exercise intervention; centre based follow up, home exercise program with no follow up and home exercise program with telephone follow up on the participants "full adherence" and "partial adherence". All analyses were conducted using Stata version 11.0. These analyses were adjusted for prescribed frequency per week and duration of program investigated, and for analysis of partial adherence, the threshold percentage used to describe the partial adherence within each study.

1.8.6 Results

A total of 11 articles were included in the final yield. (M. K. Beauchamp et al., 2013; Michael J Berry et al., 2003; Brooks et al., 2002; Cockram et al., 2006; Dunstan et al., 2006; Ries et al., 2003; Ringbaek, Brøndum, Martinez, Thøgersen, & Lange, 2010; Roessler & Ibsen, 2009; Spencer et al., 2010; Teychenne et al., 2015) (see Figure 1.3) Seven out of the eleven studies only included people with chronic obstructive pulmonary disease. (M. K. Beauchamp et al., 2013; Michael J Berry et al., 2003; Brooks et al., 2002; Cockram et al., 2006; Ries et al., 2003; Ringbaek et al., 2010; Spencer et al., 2010) Other chronic conditions represented were non-insulin dependent diabetes, osteoarthritis and cardiovascular disease. Most studies only recruited people aged between 35- 85 years. (M. K. Beauchamp et al., 2013; Michael J Berry et al., 2003; Brooks et al., 2002; Cockram et al., 2006; Dunstan et al., 2006; Ries et al., 2003; Ringbaek, Brøndum, Martinez, Thøgersen, & Lange, 2010; Roessler & Ibsen, 2009; Spencer et al., 2010; Teychenne et al., 2015) Participants were excluded if they had severe musculoskeletal conditions, cognitive impairment,(Cockram et al., 2006; Ringbaek et al., 2010) or recent exacerbations of chronic obstructive pulmonary disease.(Spencer et al., 2010)

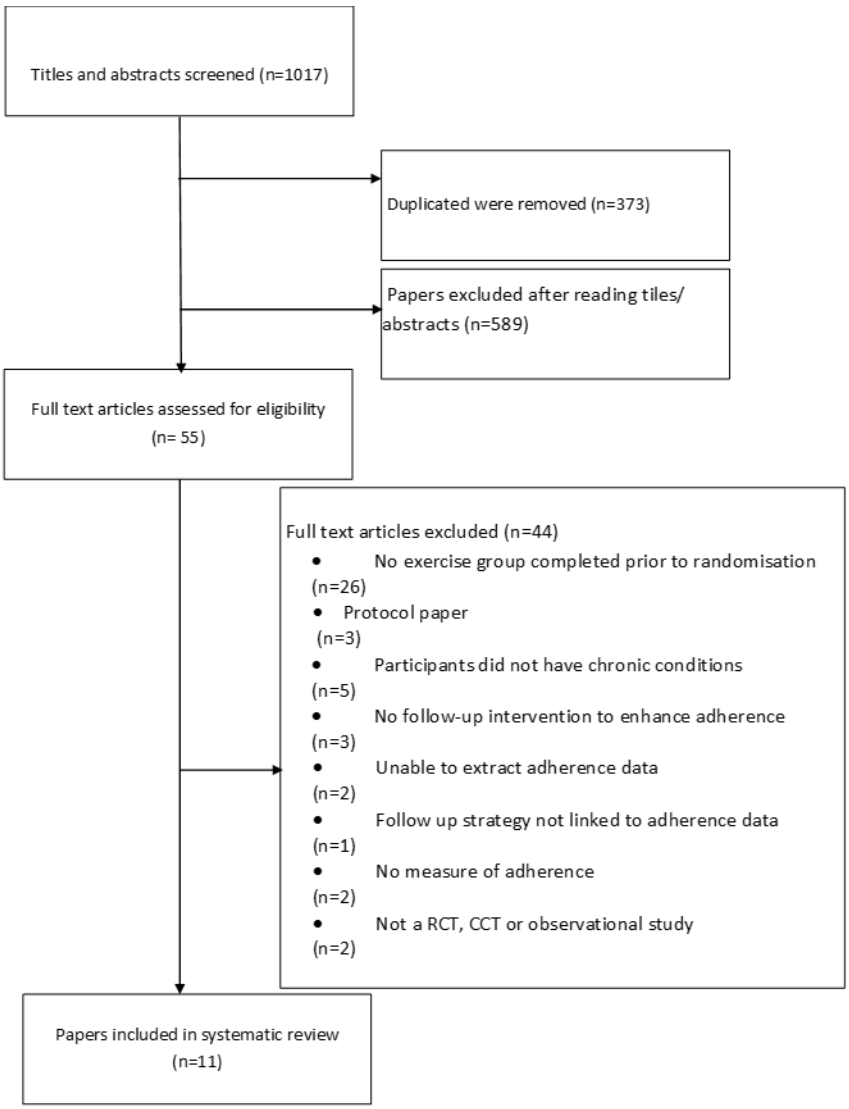

Figure 1-3 flow chart

Characteristics of included studies are presented in Table 1.4; excluded studies are listed in Appendix B.

From the included studies, four interventions for improving exercise adherence post completion of an exercise program were identified post hoc. These were centre based follow up(M. K. Beauchamp et al., 2013; Michael J Berry et al., 2003; Brooks et al., 2002; Cockram et al., 2006; Dunstan et al., 2006; Ries et al., 2003; Ringbaek et al., 2010; Spencer et al., 2010; Teychenne et al., 2015), home exercise program with telephone follow up,(Brooks et al., 2002; Cockram et al., 2006; Dunstan et al., 2006) home exercise program with no follow up,(Roessler & Ibsen, 2009; Spencer et al., 2010) and a site-based weaning program designed to gradually transition patients to an independent, off-site exercise program.

The most common setting for ongoing centre based follow up interventions was an outpatient clinic gymnasium (n=6). Home exercise programs with telephone follow up involved monthly phone calls by a health professional to monitor adherence and assist with any questions regarding the home exercise program. (Brooks et al., 2002; Cockram et al., 2006; Dunstan et al., 2006) Participants undergoing home exercise programs with no follow up were provided an illustrated logbook plus diary for recording sessions completed. (Roessler & Ibsen, 2009; Spencer et al., 2010) Carlson et al (2000) (Carlson, Johnson, Franklin, & VanderLaan, 2000) (Carlson et al., 2000) used the theoretical framework (Bandura's self efficacy theory) to underpin a site based weaning program and to enhance the patients' confidence for independent exercise.

The most common definition of adherence in the included studies was the proportion of participants completing or attending the prescribed amount of exercise sessions (study arm interventions n=10). Other adherence definitions included a "threshold" term, for example, "defined as performing at least 50% of prescribed exercise sessions". Raw adherence data was requested from the authors of two studies for which we were unable to extract data, (Elliott, Watson, Wilkinson, Musk, & Lake, 2004; Hughes et al., 2010) however no responses were received.

Full adherence

The first adherence data presented is that of "percentage fully adherent". This was the most commonly reported data that was in the included studies. Seven papers were included in this analysis. (M. K. Beauchamp et al., 2013; Michael J Berry et al., 2003; Brooks et al., 2002; Cockram et al., 2006; Dunstan et al., 2006; Ringbaek et al., 2010; Teychenne et al., 2015) The pooled proportion of "fully adherent" participants was 0.33 (95% CI= 0.31-0.35; range 0.11-0.69) with a high level of heterogeneity reported (I squared 98%, Q = 387.15, degrees of freedom (df) = 9, $p< 0.001$). Asymmetry in the forest plot was observed, which is likely to indicate the presence of clinical or methodological heterogeneity.(Higgins, Thompson, Deeks, & Altman, 2003) Results are shown in Figure 1.4, 1.5, 1.6.

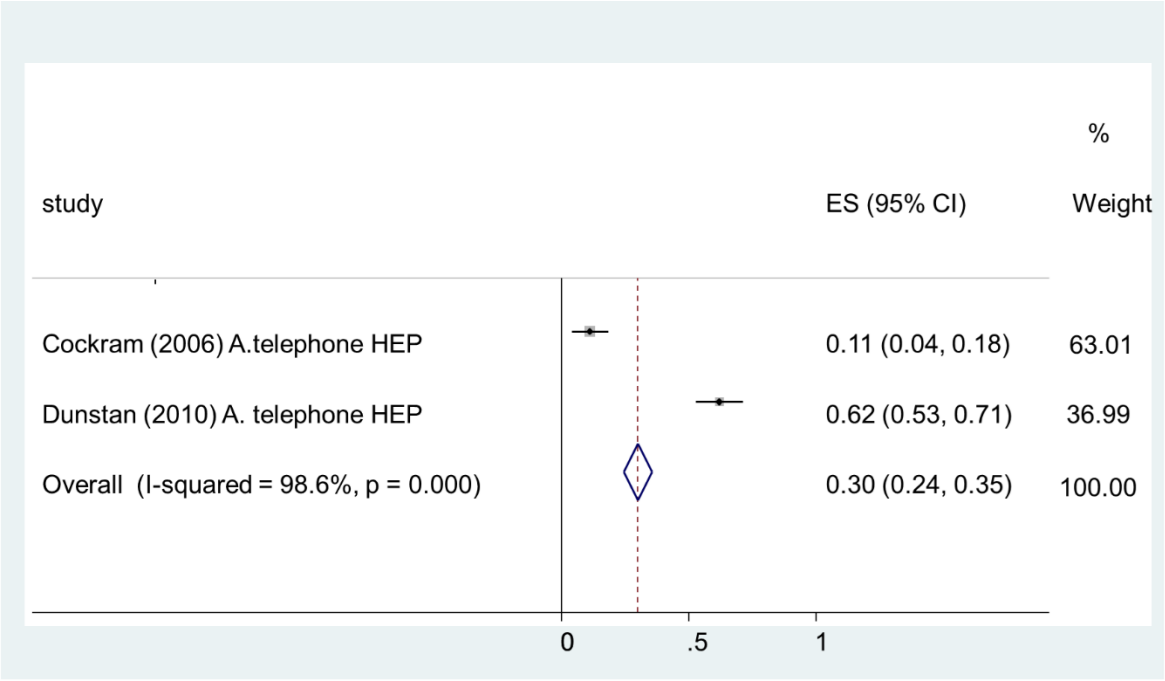

Figure 1-4 Forest plot for primary analysis random effects meta-analysis; proportion of participants with chronic health condition that were "fully adherent" to telephone only exercise interventions post completion of a supervised exercise program.

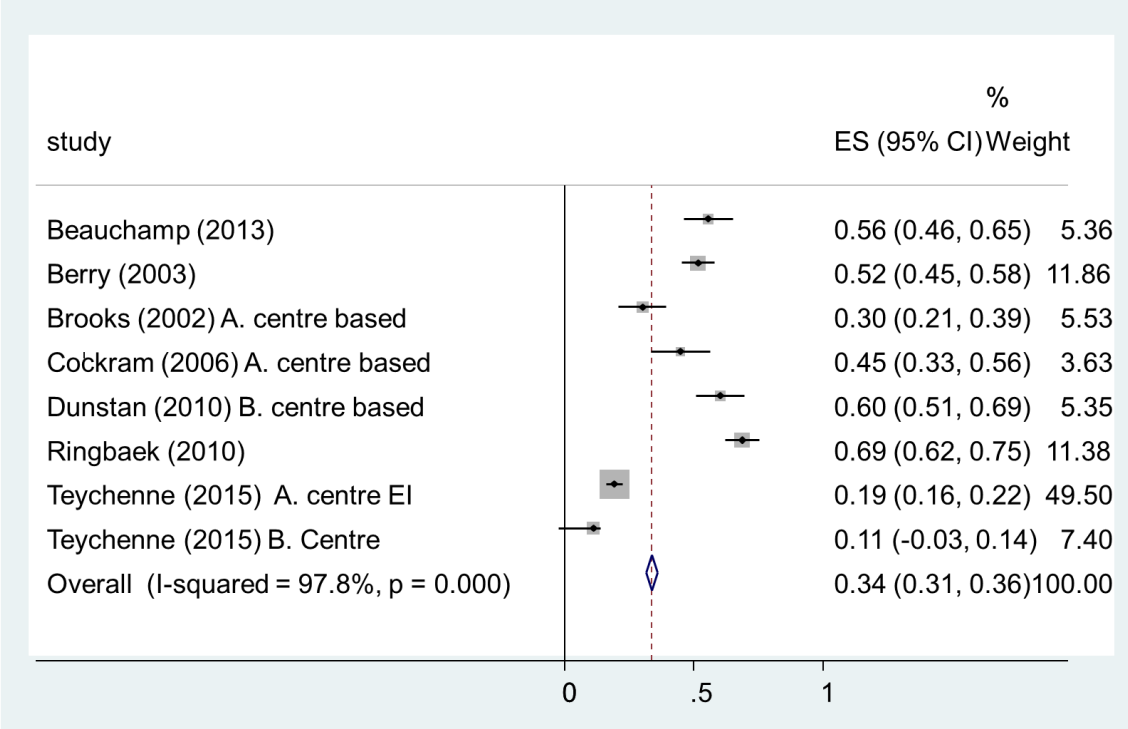

Figure 1-5 Forest plot for primary analysis random effects meta-analysis; proportion of participants with chronic health condition that were "fully adherent" to centre only exercise interventions post completion of a supervised exercise program.

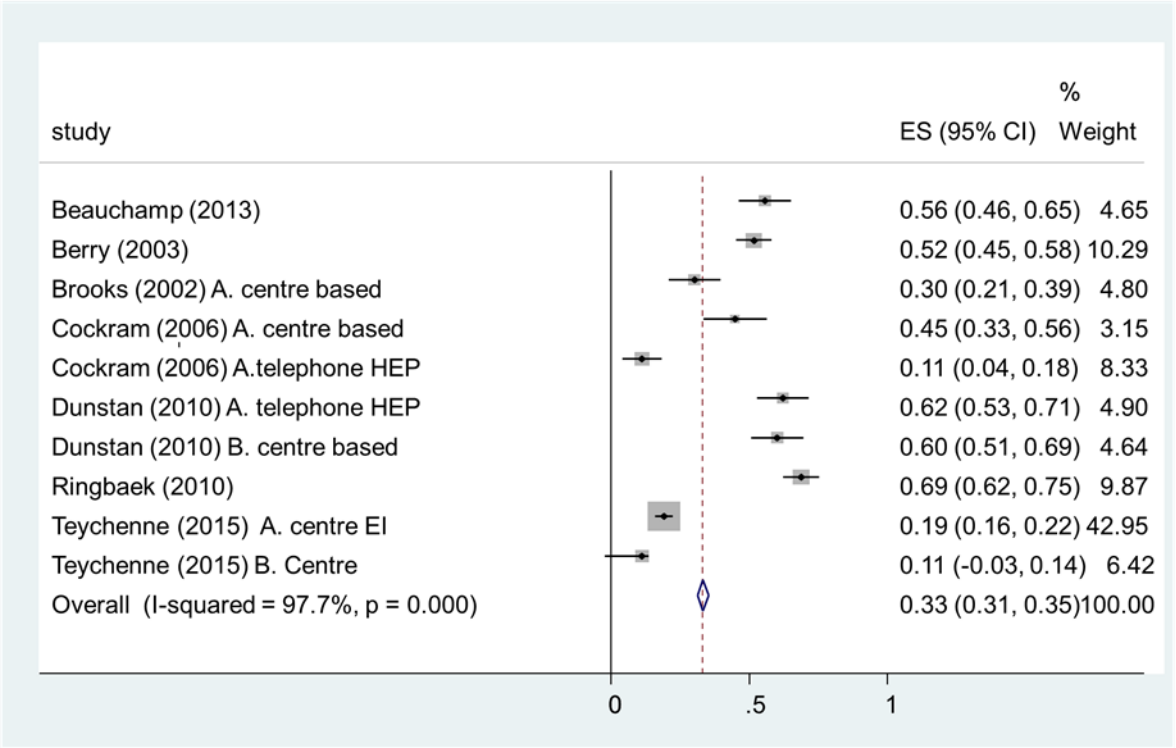

Figure 1-6 Forest plot for primary analysis random effects meta-analysis; pooled proportion of participants with chronic health condition that were "fully adherent" to an exercise intervention post completion of a supervised exercise program

A meta-regression was undertaken to identify factors that promoted a greater "percentage of fully adherent participants". Amongst studies investigating the use of a centre-based follow-up approach, the mean proportion of participants who were "fully adherent" at the 12 month follow-up was 0.34. This was compared to 0.30 for studies investigating a home exercise with telephone follow up approach. There was no significant evidence of difference between these proportions [meta-regression coefficient for effect of centre-based compared to telephone (95% CI), p-value: -0.06 (-0.48 to 0.36), p=0.75] No studies reported on the pooled proportion of "fully adherent" participants where the intervention was home-based exercise with no telephone or other follow-up.

A sensitivity analysis was undertaken which did not assume that all dropouts were non adherent, instead they were treated as missing. The pooled proportion of "fully adherent" participants in the sensitivity analysis was 0.43 (95% CI= 0.41-0.45; range 0.11-0.78), also with a high level of heterogeneity reported (I squared 98%, Q= 443.22, df = 9, p < 0.001). (Higgins et al., 2003) This higher adherence rate is expected, as the intervention dropouts are excluded in the sensitivity analysis. A meta-regression of this sensitivity analysis was comparable to the primary analysis indicating that the factors associated with full adherence were not sensitive to the assumptions made about whether the missing data represented participants who were adherent or not.

Partial adherence

The most commonly reported definition of threshold percentage was whether participants completed at least 50% of prescribed sessions (see Table 1.4). Four papers were included in this analysis(Brooks et al., 2002; Ries et al., 2003; Roessler & Ibsen, 2009; Spencer et al., 2010), of which only one overlapped with the analysis of full adherence.(Brooks et al., 2002) The pooled proportion of "partially adherent" participants was 0.37 (95% CI= 0.34-0.41; range 0.24-0.75) with high level of heterogeneity reported (I squared 96.1%, Q = 101.57, df= 4, p< 0.001). (Higgins et al., 2003)

The pooled proportion of "partially adherent" participants in the sensitivity analysis was 0.65 (95% CI= 0.62-0.69; range 0.5-0.92), also with a high level of heterogeneity reported. (I squared 96.2%, Q= 105.22, df = 4, p < 0.001).(Higgins et al., 2003) This results indicates that our pooled estimate of partial adherence across studies is quite sensitive to the assumptions made as to whether dropouts were adherent or not.

One study described the mean proportion of participants who were "partially adherent" at the 12 months where a telephone follow-up intervention was investigated. This proportion was 0.24.(Brooks et al., 2002) This was compared to 0.74 pooled from two studies investigating a centre based follow up approach.(Ries et al., 2003; Spencer et al., 2010) There was no significant evidence of difference between these proportions [meta-regression coefficient for effect of telephone compared to centre-based (95% CI), p-value: -0.49 (-1.53 to 0.54), p=0.104].

The proportion partially adherent in studies investigating home exercise program with no follow up approach was 0.29. There was no significant evidence of difference between this proportion and that from programs with telephone based follow up [meta-regression coefficient for effect of telephone compared to no follow up (95% CI), p-value: -0.18 (-3.58 to 3.22), p=0.62]. Sensitivity analyses for this meta-regression were comparable to the primary analysis.

Amongst studies investigating the use of a centre-based follow-up approach, the mean proportion of participants who were "partially adherent" at the 12 month follow-up was 0.74. There was no significant evidence of difference between this and the proportion partially adherent to a home program with no follow up [meta-regression coefficient for effect of centre-based compared to nothing (95% CI), p-value: 0.32 (-0.35 to 0.98), p=0.175]. Sensitivity analyses for this meta-regression were comparable to the primary analysis.

One study (Carlson et al 2000)(Carlson et al., 2000) reported the number of sessions completed per participant but not the number of participants who completed or partially completed the "goal" number of sessions. These authors reported that their site-based weaning program designed to gradually transition patients to an independent, off-site exercise program led to completion of an average of 112 (sd 29) exercise session per participant over 6 months compared to 98 (sd 33) for those who received the traditional, site-based program. This evidence of difference was not statistically significant.

Risk of bias assessment

An assessment of risk of bias for each included study is presented in Table 1.2. Most included studies were of low quality according to the Cochrane Collaboration tool for assessing risk of bias. Results for the key domains of selection bias, blinding, and attrition bias are summarised below.

Four studies were classified low risk of selection bias according to the Cochrane risk of bias assessment. Berry et al (2003)(Michael J Berry et al., 2003)and Spencer et al (2010)(Spencer et al., 2010) used a randomised algorithm generator where Teychenne (2015)(Teychenne et al., 2015) used cluster randomisation. Brooks et al (2002)(Brooks et al., 2002) stratified each participant by using baseline 6 minute walk test, then used a random numbers table. The remainder of the studies (Carlson et al., 2000; Cockram et al., 2006; Dunstan et al., 2006; Ries et al., 2003; Ringbaek et al., 2010; Roessler & Ibsen, 2009) were classified unclear risk of selection bias as their methods were not adequately described.

Blinding of participants or personnel were not adequately reported in any studies apart from (Michael J Berry et al., 2003) and (Teychenne et al., 2015) who reported that staff members were blinded to the participants group assignment.

Six studies were classified low risk of attrition bias due to low participant numbers lost to follow up. (Carlson et al., 2000; Dunstan et al., 2006; Ries et al., 2003; Ringbaek et al., 2010; Spencer et al., 2010; Teychenne et al., 2015) Studies by (Cockram et al., 2006) and (Brooks et al., 2002) reported loss to follow of 25 and 22 percent respectively and were classified high risk of attrition bias. Three studies failed to report

on attrition bias and were classified as unclear risk of attrition bias. Six month data was collected but not reported by (Roessler & Ibsen, 2009), therefore was classified high risk. The remaining studies were classified unclear risk of reporting bias. No study published a protocol paper.

1.8.7 Discussion

This review found no evidence of difference in the adherence rates observed amongst the four follow up strategies investigated. The proportion of participants who were fully adherent to an exercise program prescribed after the completion of a supervised exercise program was approximately 33%. The proportion who were partially adherent was estimated to be 37%. This discrepancy can be explained by the heterogeneity in reporting of studies included in this review and there was little overlap in the studies that contributed to these two estimates. It should also be noted that only one study articulated a theoretical foundation for follow up strategies to bring about greater adherence indicating that further work in this space is required before definitive conclusions regarding specific approaches can be made.

We also found no evidence of difference in the proportion of participants who were fully adherent to an exercise program at 12 months post completion of the supervised exercise program when comparing centre-based follow-up (pooled proportion fully adherent=0.34) to telephone follow up (pooled proportion fully adherent=0.30, difference p-value=0.75). Although non-significant, the slightly higher proportion of centre based adherence may be explained by the additional social interaction with other participants or the health professional in centre based follow up. This is consistent with previous studies that highlighted the major importance of social contact and support of an exercise group, especially among older women. (Clark, 1999; Hirvensalo, Lampinen, & Rantanen, 1998; McAuley, Jerome, Elavsky, Marquez, & Ramsey, 2003) In contrast, a Cochrane review by Ashworth et al (2005) (Ashworth, Chad, Harrison, Reeder, & Marshall, 2005) found home based programs (with or without telephone support) showed a 68% adherence rate at two year follow up compared to 36% adherence in the centre based intervention. This review however, did not specifically focus on people who had recently completed a supervised exercise program.

The financial costs or inability of older adults to reach exercise facilities may be a major barrier to ongoing adherence. (Burbank & Riebe, 2014; McPherson, 2010) Telephone follow up may be a more effective adherence intervention for older people with transport barriers who struggle to access exercise facilities. Further research is required to fully examine adherence rate and cost effectiveness of providing centre based follow up compared to telephone based follow up after completing a supervised exercise program.

A meta-regression was unable to be conducted to analyse the relationship between the quantity of health professional involvement and adherence due to the small number of articles that had this data. It was hypothesised that an increase in health professional contact would correlate with an increase of exercise adherence. Further research is required to analyse the relationship between frequency of health professional contact and adherence.

We were also unable to conduct a meta-regression to analyse the relationship between the health profession delivering the intervention and exercise adherence due to small number of articles in this review. However, in the majority of included studies (seven out of eleven) the intervention was delivered by a physiotherapist or an exercise physiologist. When not provided by a physiotherapist or an exercise physiologist, programs were provided by a trained fitness instructor. Exercise adherence has been found to improve in older adults whose program was prescribed by physicians or other health care professionals. (Hirvensalo et al., 1998) Adherence rates have been found to be 3 times higher after being prescribed by health professionals compared to non-health professionals due to interpersonal relationship factors such as trust and expected knowledge in treating chronic health conditions. (Safran et al., 1998) Further research is required to analyse the relationship been health professionals delivering the intervention and adherence.

1.8.8 Limitations

This review was limited by the varying definitions of adherence used in the included studies. Further, adherence to centre based exercise is relatively easy to record but adherence to home exercise program relies on self-reported log books or surveys. It is likely that this approach results in over-estimates of adherence rates due to social desirability effects and obsequious responses provided by participants. All studies in this review used self-reporting methods and no study reported any inter-reliability of adherence measurement. Compounding this issue; home exercise interventions in this review predominantly include a walking program which may be more susceptible for overestimating adherence rates as clients may not be able to decipher between prescribed walking program and incidental walking. There is a clear need for a standardised validated measure of exercise adherence that is responsive to change for future studies involving adults with chronic disease. Activity tracker Global Positioning System wrist watches or pedometers (for walking programs) may induce greater accuracy in self-reported adherence in future studies.

Most included studies were of low quality. Two studies were judged to be high risk of attrition bias, reporting up to 25% drop out rates after completion of a 12 month intervention. (Brooks et al., 2002; Cockram et al., 2006) Seven out of eleven studies solely focused on people with chronic obstructive pulmonary disease. Acute exacerbations and re-hospitalisation may have further contributed to attrition bias in this review. Spencer et al (2010) (Spencer et al., 2010) reported a mean hospital of admission due to chronic obstructive pulmonary disease exacerbation of 2.3 +/-3 for each client during a 12 month exercise intervention further highlighting the progressive nature of chronic obstructive pulmonary disease.

Another limitation of this review is the potential bias created from performing a meta-analysis and meta-regression on a small numbers of trials. Figure 1.4 demonstrates a large amount of heterogeneity as we are comparing only two studies in this sub group. This may not be an accurate representation of the underlying "true" effect of the full adherence intervention. However, the aim of this review is pool together the limited amount of trials to reflect the "best available evidence" to date. The small number of studies also precluded sub group analyses to evaluate the relationship between program factors such as frequency, duration or chronic conditions on exercise adherence. Furthermore, there is a risk of missing relevant studies by using the Australian Institute of Health and Welfare (AIHW) Focus Conditions (excluding chronic kidney disease, oral diseases) for the participant[a] search terms. Studies including cancer, multiple sclerosis or Parkinson's disease may have been missed.

The majority of studies were reported high risk of blinding participant or personnel due the inability to blind participants in real life gymnasium settings. There were eight studies that did not adequately report their selection procedure and were classified as unclear risk of bias.

1.9 Conclusion to systematic review

This systematic review presented the current evidence of the most effective strategy to maintain ongoing exercise adherence in adults with chronic diseases that have previously completed a supervised exercise program by a health professional. In total, eleven studies in this review were included, mostly involving patients with chronic obstructive pulmonary disease. Most included studies were of low quality, as identified by our assessment of risk of bias. Further research is required of higher quality non pulmonary disease only studies to determine which exercise adherence intervention is most effective for clients with chronic health conditions who have already completed a supervised exercise program. Understanding the exercise adherence strategies that are most effective in influencing exercise among older adults who have completed a supervised exercise program is extremely important for health professionals because low rates of post-program exercise adherence are likely to limit the benefits obtained.

1.10 Conclusion Chapter 1

This introductory chapter has presented the evidence that low levels of physical activity contributes to the development and progression of up to 35 chronic disease. The next section provided evidence to suggest that exercise can mitigate and reverse the progression of most chronic diseases. The Australian health care system commonly provides exercise interventions that are short term, ie 4-6 weeks. There is evidence to suggest that after the completion of short term exercise programs, exercise adherence declines, along with the clinical benefits initially gained.

The review found two main strategies for maintaining full adherence; centre based follow up and home-based exercise program with telephone follow up. A meta-analysis found no difference in the proportion of full adherence to a 12 month exercise program between these two strategies. The preliminary work has demonstrated there is no clearly effective strategy to maintain exercise adherence of the two leading strategy; home exercise program with telephone follow up versus centre based exercise program.

1.11 Thesis proposal

1.11.1 Research overview

The main objective of this thesis was to compare the effectiveness and cost-efficiency of gym-based versus home-based exercise with telephone follow up amongst adults with chronic conditions that have completed a short-term exercise program supervised by a health professional. I also aimed to identify and compare participants' perceptions about their own motivation, capacity and opportunity to adhere to their allocated exercise program to see if this differed by group, and whether participants' insights could inform future exercise intervention designs.

1.11.2 Research Aims

Aim 1 - To compare the clinical effectiveness of home-based exercise with telephone follow up compared with gym follow up amongst adult with chronic conditions that have completed a short term supervised exercise program by a health professional

> This aim is addressed in Chapter 3*, The clinical effectiveness of home-based exercise with telephone follow up compared with gym follow up amongst adults with chronic conditions that have completed a short term supervised exercise program by a health professional.*

Aim 2 – To compare the economic efficiency of *home-based exercise with* telephone follow up compared with gym follow up amongst adult with chronic conditions that have completed a short term supervised exercise program by a health professional.

> This aim is addressed in Chapter 4, *Economic efficiency of home-based exercise with telephone follow up compared with gym follow up amongst adult with chronic conditions that have completed a short term supervised exercise program by a health professional*.

Aim 3– To identify and compare participants' perceptions about their own motivation, capacity and opportunity to adhere to an allocated exercise program during either a gym-based or a home-based exercise program with telephone follow-up.

> This aim is addressed *in Chapter 5, Qualitative analysis of home-based exercise with telephone follow up compared with gym follow up amongst adult with chronic conditions that have completed a short term supervised exercise program by a health professional.*

1.11.3 Overview of following chapters

Chapter 2 will present each study's methods and rationale. Chapters 3 to 5 present the three research studies in chronological order. Chapter 6 presents a summary of the main findings from the research program and the implications of these findings. This chapter includes a discussion of the strengths and weaknesses of the thesis and recommendations for future research

This thesis contains published and unpublished works, presented in a traditional thesis format. Supporting materials referred to in the thesis are in associated appendices.

2 Chapter 2: Methodology

2.1 Introduction

In the previous chapter, it was established that ongoing exercise can mitigate against many of physiological, psychological, functional and social effects of chronic disease and ageing. The systematic review found no clearly superior strategy to maintain exercise adherence in people following completion of a short-term supervised exercise program for a chronic health condition. It concluded with the aims of this thesis which were:

Aim 1 - To compare the clinical effectiveness of home-based exercise with telephone follow up compared with gym follow up amongst adult with chronic conditions that have completed a short term supervised exercise program by a health professional

Aim 2 – To compare the economic efficiency of home-based exercise with telephone follow up compared with gym follow up amongst adult with chronic conditions that have completed a short term supervised exercise program by a health professional.

Aim 3– To identify and compare participants' perceptions about their own motivation, capacity and opportunity to adhere to an allocated exercise program during either a gym-based or a home-based exercise program with telephone follow-up.

This chapter describes the methods used in the each of the studies included in this thesis.

2.2 Methods for Main Study (Randomised controlled trial)

Setting

This randomised controlled trial was conducted at Cardinia Casey Community Health Service, South East Melbourne, Australia. Those referred to this service typically have: multiple co-morbidities; poor or declining mobility; physical de-conditioning; or a combination of these problems. This service aims to provide people with the tools they need to attain independence and self-management and maximise their ability to participate in normal daily tasks and life roles. Services may be provided individually or in groups by a multi-disciplinary team including physiotherapy, exercise physiologist, occupational therapy, speech therapy, dietetics, social work, neuropsychology, nursing, rehab consultant and allied health assistants. Exclusion criteria for the centre include eligibility for an alternative privatised service (e.g. via the Transport Accident Commission or WorkCover insurance schemes)

Participants

Inclusion Criteria

Participants were recruited using a convenience strategy from a pool of adults who had completed a 6-week exercise program at Cardinia Casey community health service which aimed to improve physical, sensory, cognitive, psychological and social functional levels. Their program prior to this trial consisted of one-hour group exercise sessions, with participants encouraged to attend three sessions per week. Each participant was provided with a home-based exercise program at the conclusion of the supervised exercise program.

Potentially eligible participants were invited verbally to participate by their treating exercise physiologists (including the PhD candidate) immediately after the completion of the supervised group exercise program. Participants with any chronic health conditions were invited to participate in the study.

Exclusion Criteria

Participants were excluded if acute psychiatric impairment or cognitive impairment made the person unsuitable for participation in a gym or home-based exercise program, as determined by health service staff. Partners and/or couples were also excluded from participation.

Randomisation and Allocation concealment

Randomisation involved the investigator opening a sealed, opaque envelope containing the random allocation sequence, which was developed by a separate investigator with no knowledge of participants' baseline results. This sequence was set out in permuted blocks of sizes 4, 6, and 8, and was stratified by the participant's primary chronic disease diagnosis type (pulmonary, musculoskeletal, diabetes, other). Participants were randomised to one of the two 12-month exercise interventions: gym-based or home-based with telephone follow-up.

Data collection

Exercise physiologists (including the PhD candidate) collected baseline data for this trial upon discharge from the short-term supervised program. A blinded research assistant conducted the reassessments at 3, 6, 9 and 12 months. Refer to table 2.1. Participants were not blinded to group allocation, therefore their self-reported outcomes could not be considered to be blinded.

Interventions

Gym-based exercise program

Participants allocated to the gym-based intervention were given a 12-month, individualised, exercise program. This was supervised at the gym by an exercise physiologist (including the PhD candidate) from the community health service Monday to Friday for 2 hours per day. This means that there was a person present at the gym with whom the participant already had a pre-established relationship from when they had completed the initial short-term supervised exercise program. Participants were encouraged to attend during these supervision times when the exercise physiologist attended the gym. However, participants were able to attend independently during off peak times at the gym (Monday to Friday 8am - 4 pm). Each participant was encouraged to complete a one-hour exercise session, 3 times per week. They were required to pay the standard casual entry fee of $5 per visit to the gym. The exercise prescription adhered to the American College of Sports Medicine (ACSM) guidelines for chronic health conditions. (Moore et al., 2016)

The prescribed exercise included strengthening, aerobic and stretching exercise components. The strengthening component involved 40 minutes of six to eight strength training exercises for the upper and lower body (eg, leg press, calf raise, bicep curl, triceps push-down, lateral pull-down, chest press or scapula retraction) using pin-loaded resistance equipment unless contraindicated. Participants were prescribed a two-set repetition maximum per exercise set at a moderate intensity of approximately 60% of their 10 repetition maximum. The aerobic component of the exercise involved up to 15 minutes of stationary bike, treadmill or cross trainer. The rating of perceived exertion scale was used to monitor a safe "moderate" intensity. (Borg et al., 1982) The stretching component involved 5 minutes of upper and lower limb stretching (eg, pectoral, shoulder, calf, hamstring and quadriceps) with two repetitions of each static stretch prescribed for 30 seconds. The healthcare professionals providing the intervention were trained in the Health Coaching Australia model that use motivational interviewing techniques, solution focused

coaching and cognitive behavioural therapy techniques to identify techniques and address behavioural, emotional, situational and cognitive barriers to exercise adherence. (Gale, 2010)

Home-based program with telephone support

Participants allocated to the home-based intervention were also given a 12-month, individualised, exercise program. Each participant was encouraged to complete a one-hour exercise session, 3 sessions per week, at home outside the telephone supervision times that suited the participant. The home-based exercise program was supervised via 5 telephone calls over the first 10 weeks, approximately 25 to 30 minutes in duration. The total time in minutes to complete the 5 phone calls for each participant was comparable to that spent supervising each participant in the gym over a 12-month intervention period. The exercise physiologist supervising the telephone intervention was also trained in the Health Coaching Australia Model. The same exercise physiologists (including the PhD candidate) who provided supervision for the gym-based program also provided the supervision for the home-based program, ensuring equivalence in the experience and educational background of the providers of each of these interventions.

The exercise prescription aimed to be comparable to that of the gym-based program. It also adhered to the ACSM guidelines for chronic health conditions, (Moore et al., 2016) with strength, aerobic and stretching components comparable to the gym-based program. The strength training component involved six to eight exercises for the upper and lower body (eg, sit to stand, calf raise, bicep curl, triceps push-down, lateral pull-down, chest press or scapula retraction) using body weight or an elastic exercise band[a] to provide resistance. The aerobic component included community walking or, if participants had access to their own exercise equipment such as a stationary bike, this was incorporated.

Health coaching Australia parallel intervention in both Gym-based exercise program and Home-based program with telephone support

The exercise physiologists providing the intervention were trained in the Health Coaching Australia Model (Gale, 2010) that uses behavioural change tools and techniques to identify and address behavioural, emotional, situational and cognitive barriers to exercise adherence. Health coaching Australia uses three distinct stages of change. The first stage is to form a behavioural intention to change. The theoretical models that underpins this stage includes the health belief model (Rosenstock, 1974), theory of planned behaviour (Ajzen, 1991), social cognitive theory (Bandura, 2001), protection motivation theory (Maddux & Rogers, 1983), self-regulation theory (Reeve, Ryan, Deci, & Jang, 2008), and decisional balance. (Janis & Mann, 1977) The second stage is to convert the goal intention into action and maintenance. Theoretical models that underpins this stage includes cognitive behavioural therapy (Beck, 1993), solution-focused coaching (Greene & Grant, 2003), and relapse prevention (Cummings, Gordon, & Marlatt, 1980). Theoretical models to support the third stage; patient-centred approach that focuses on client autonomy and intrinsic motivation include theories such as motivational interviewing (Miller & Rollnick, 2012), self-determination theory (Deci & Ryan, 2008), and intrinsic motivation (Vansteenkiste, Lens, & Deci, 2006).

Outcome measures

Table 2-1 Summary of outcome measures

Construct	Descriptor	Measurement Name	Scaling
Health condition	Health care costs	**Costs - Consumer**	Amount in AUD spent on health care from baseline to twelve months.
Body Structure and Function	Weight Maintenance	**BMI**	Weight in kilograms /Height in metres squared
	Muscle Power	**Sit to Stand**	15 second sit to stand
	Mental Functions	**HADS**	Score out of 21
	Muscle Endurance	**6 min walk test**	Measured in metres
	Adverse Outcomes	**Pain or Musculoskeletal injury**	Type and number of injury due to exercise program
Activity/Participation	Productivity/work	**Health and Labour Questionnaire**	Amount in AUD that the health problem affected paid and unpaid work (including domestic tasks)
	Exercise adherence	**Phone-FITT**	Amount and Intensity of Exercise
		Gym attendance	Number of session attended
		Home Exercise Program Completed	Number of exercise sessions via participants' log book
Environmental Factors	Social Isolation	**Friendship Scale**	Score out of 24
Quality of Life & Economic Variables	Global	**EQ-5D**	EQ5-D utility score out of 1.0 EQ VAS score from 0-100
	Value	**Costs - Service**	Total amount in AUD of providing either the home based or centre based service

AUD = Australian Dollar

Primary outcome in Randomised Controlled Trial-Chapter 3 and Economic Evaluation-Chapter 4

European Quality of Life Instrument

Health-related quality of life was assessed using the European Quality of Life Instrument (EQ-5D-3L). (Rabin & Charro, 2001) This questionnaire contains five multiple-choice questions and a 100-point overall health state visual analogue scale (VAS). The five questions reflect mobility, personal care, usual activities, pain/discomfort and anxiety/depression. The respondent selects one of three ordinal statements to describe their health for each. In order to obtain an overall score the Dolan utility calculator (Dolan & Roberts, 2002) was applied. A utility score is determined where 0 represents death and 1 perfect health. Test- retest reliability for community-based adults following stroke is Intra-Class Coefficient (ICC) =0.83 at 3 weeks and ICC=0.86 at 3 months. (Dorman, Slattery, Farrell, Dennis, & Sandercock, 1998) A minimum clinically important difference using this calculation approach for the EQ-5D-3L amongst mixed chronic diagnosis groups has been estimated to be 0.074. (Walters & Brazier, 2005)

Secondary outcomes for Randomised Controlled Trial-Chapter 3

Friendship scale

Social activity was measured using the Friendship Scale, (Hawthorne, 2006) a short and user-friendly instrument that measures six dimensions contributing to social isolation and social connection. A score range is between 0 and 24; with higher scores representing better social connectedness. Cut off ranges has been suggested as: very socially isolated (0-11), isolated or low level of social support (12-15), some social support (16-18), socially connected (19-21), and very socially connected (22-24) (Hawthorne, 2006). To date, there is limited reliability and validity data. (Beer et al., 2016)

Hospital Anxiety and Depression Scale

Depression and anxiety were measured using the Hospital Anxiety and Depression Scale (HADS). (Zigmond & Snaith, 1983) The HADS includes 14 items, seven of which relate to an anxiety subscale and seven to a depression subscale. Each item is scored between 0 and 3, and a sub-scale score above 8 indicates a possible case and a score above 10 a probable case. Researchers in trial involving community based participants in a stroke unit four months post stroke reported high internal consistency with values of Cronbach's a (α)= 0.89 in the anxiety subscale and α= 0.83 depression subscale respectively. (Sagen et al., 2009) A study of coronary artery disease participants used the hospital anxiety depression tool as a screening tool for depression and found an internal consistency of α= 0.81 (Stafford, Berk, & Jackson, 2007). The HADS is deemed an acceptable screening tool for post-stroke depression, with high sensitivity (91.7%) and specificity (65.3%) at the optimal threshold or score of 11 or more. (Aben, Verhey, Lousberg, Lodder, & Honig, 2002)

Body Mass Index

Body mass index (BMI) was determined by body weight in kilograms divided by height in metres squared. (Deurenberg, Weststrate, & Seidell, 1991) BMI values are classified in both males and females as: underweight (less than 18.5); normal weight (between 18.5 and 24.9); overweight (25 to 29); obese class I (30 to 34.9); obese class II (35 to 39.9), obese class III (greater than 40). A study of 998 adults with metabolic syndrome found a Pearson's moment correlation coefficient between body mass index and waist circumference of r=-0.887. (M Chakraborty & Chakraborty, 2007).

The 15-second sit-to-stand

The 15-second sit-to-stand (STS) test (Bohannon, 1995) was included, as it is commonly used to measure lower limb strength in older people. The test–retest reliability was established to be excellent (ICC = 0.96) in a study assessing older adults with knee or hip osteoarthritis. (Lin, Davey, & Cochrane, 2001) In a study

examining mobility tests for predicting multiple falls in community dwelling older adults, good test–retest reliability was reported ICC = 0.89. (Tiedemann, Shimada, Sherrington, Murray, & Lord, 2008)

6-minute walk test

The 6-minute walk test (6MWT), (Laboratories, 2002) which measures the distance a participant is able to walk in 6 minutes, was performed once per participant at each time point using the American Thoracic Society guidelines. The test–retest reliability of the 6-minute walk test in stroke participants was ICC =0.973 for all the clients in the study, ICC =0.971 for clients with Functional Independence Measure locomotion scores of greater than 5 (Fulk, Echternach, Nof, & O'Sullivan, 2008) The test-retest reliability of the 6 minute walk test was ICC =0.90 at baseline, α = 0.88 at 18 week and ICC =0.91 at 43 weeks for participants diagnosed with heart failure. (Demers, McKelvie, Negassa, & Yusuf, 2001)

Phone-FITT

Physical activity was measured using the Phone-FITT, (Gill, Jones, Zou, & Speechley, 2008) which includes self-reported questionnaire about the frequency, intensity, time and type of physical activity undertaken. The Phone-FITT allows respondents to report on household activity (such as cooking, cleaning and gardening), recreational physical activity (such as lifting weights, playing sport physical activity), and total physical activity. A total physical activity (PA) summary score between 0 and 209 can be derived from the frequency and duration data by multiplying the two across all questions and adding the products. A higher score signifies greater participation in physical activity. The Phone-FITT reported construct validity in older adults of 0.56 compared to actigraph measures, -0.2- Step test and -0.12-age (Gill et al., 2008). Test-retest reliability for the Phone fit administered seven days apart, total score was ICC =0.77; household scores ICC = 0.84 and recreational scores ICC =0.88. (Gill et al., 2008)

Secondary outcomes for Economic evaluation -chapter 4

Health and Labour Questionnaire

The Health and Labour Questionnaire collects quantitative data to estimate indirect productivity losses in relation to indirect paid and unpaid labour or work. (Hakkaart-van Roijen & Bouwmans, 2007) This questionnaire is divided into four sections: hours related to absence from work; hours related to reduced productivity of paid work; hours related to unpaid production; and reasons for not being able to complete both paid and unpaid labour. The questionnaire is a standardised non disease specific and available in languages English, Swedish, Dutch and French. (Hakkaart-van Roijen & Bouwmans, 2007)

Attendance for Chapter 3

Attendance at the community-based fitness centre over the twelve months was measured via gym scanning software that recorded client attendance. Participation in alternate forms of physical activity was measured at follow-up assessments at 3, 6, 9 and 12 months, with a patient-recorded log book. Participation in home-based exercise program was measured using patient log and collated at 3, 6, 9 and 12 month assessments.

Adverse events for Chapter 3

An adverse event was defined as any injury or exacerbation of existing illness that required medical attention while participating in either intervention and was measured using the patient log book at 3, 6, 9 and 12 months.

Sample size

Chapter 3 and 4

A sample size of 52 participants per group was required for this experiment to have 90% power to detect a 7-point change in the EQ-5D-3L visual analogue scale of global health-related quality-of-life at the 12-month follow-up assessment. Many minimal clinically important difference levels have been established for the EQ-5D-3L VAS across a range of patient populations with chronic disease, though a 7-point change is a standard commonly employed. (McPhail, Beller, & Haines, 2008) A standard deviation of 11 points was used on the basis of a pre-trial survey of 20 patients within the target group conducted by the investigators. A 10% participant attrition rate was accommodated for, thus we aimed to recruit 57 participants per group into this study.

Chapter 5

Details on sample size are provided in chapter 5.

2.3 Data analysis

Randomised Controlled Trial

Each of the outcomes were compared between groups using linear regression analyses. Alpha criterion level was set at $p = 0.05$. All analyses were conducted using Stata version 11.0. Further details are provided in chapter 3.

Economic Evaluation

A comparative, incremental cost-utility analysis was conducted. The base analysis was conducted from the societal perspective. Uncertainty in this incremental cost-utility analysis was investigated using bootstrap resampling. An alpha criterion level was set at $p=0.05$ for all analyses. All analyses were conducted using Stata version 11.0. Further details are provided in chapter 4

Qualitative Analysis

A modified thematic framework was used to analyse the data. Five stages of coding were completed: i) Familiarisation; ii) Identifying a thematic framework; iii) Indexing; iv) Charting; and v) Mapping and Interpretation. An iterative process was then used to test and retest the thematic framework. Further details are provided in chapter 5

2.4 Ethical Consideration for Chapter 3, 4 and 5.

This trial was registered on the Australian New Zealand Clinical Trials Register: ACTRN. ACTRN12610001035011. We received ethical clearance from The Southern Health Medical Research Ethics Committee; Number: 10187L

3 Chapter 3-Randomised Controlled Trial

The clinical effectiveness of home exercise program with telephone follow up compared with gym follow up amongst adults with chronic conditions that have completed a short term supervised exercise program by a health professional.

3.1 Preface to randomised controlled trial

The following text is adapted from an article published in 2017. Jansons, P., Robins, L., O'Brien, L., & Haines, T. Gym-based exercise and home-based exercise with telephone support have similar outcomes when used as maintenance programs in adults with chronic health conditions: a randomised trial. *J Physiother*. 2017. 63 (3)154–160. doi: 10.1016/j.jphys.2017.05.018

Declaration for Thesis Chapter 3

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2017) Gym-based exercise and home-based exercise with telephone support have similar outcomes when used as maintenance programs in adults with chronic health conditions: a randomised trial. J Physiother. 2017. 63 (3)154–160. doi: 10.1016/j.jphys.2017.05.018

Monash University

Declaration by candidate

In the case of Chapter 3, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication.	80%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**	**Extent of contribution (%) for student co-authors only**
Terry Haines	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	10%
Lisa O'Brien	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	5%
Lauren Robins	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	5%

Candidate's Signature	[redacted]	**Date** 24/4/18

Declaration by co-authors

The undersigned hereby certify that:

(1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(4) there are no other authors of the publication according to these criteria;
(5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	Allied Health Research Unit, Kingston Centre, Warrigal Rd, Cheltenham 3192

Signature 1	[redacted]	Lisa O'Brien	**Date** 24/04/2018
Signature 2		Terry Haines	24/04/2018
		Lauren Robins	24/04/2018

3.2 Randomised Controlled Trial

3.2.1 Abstract

Research aim

To investigate the effectiveness of gym-based exercise versus home-based exercise with telephone follow-up amongst adults with chronic conditions that have completed a short-term exercise program supervised by a health professional.

Design

We conducted a randomised controlled trial with concealed allocation, intention-to-treat analysis, and blinded outcome assessment at baseline and at 3, 6, 9 and 12 months.

Participants

The participants were recruited following a 6-week exercise program at a Community Health Service

Intervention

One group of participants received a gym-based exercise program for 12 months (gym group). The other group received a home-based exercise program for 12 months with telephone follow-up for the first 10 weeks (home group). Participants were encouraged to complete three, 60 minute sessions per week.

Outcome measures

Outcome measures included European Quality of Life Instrument (EQ-5D), the Friendship scale, the Hospital and Anxiety and Depression Scale, Phone-FITT, 6-minute walk test, Body Mass Index and 15-second sit-to-stand test.

Results

Demographics of the participants were: Home group (n=51), mean age 66 years, number of female (n=38) compared with gym group (n=54), mean age 68 years, number of female (n=29). There was no significant difference between study groups in the primary outcome (EQ-5D visual analogue scale, 0 to 100) across the 12-month intervention period, with an estimate (adjusted regression coefficient) of the difference in effects of 0 (95% CI –5 to 4). The gym group demonstrated slightly fewer symptoms of depression over the 12-month period compared to the home group (mean difference 0.8 points on a 21-point scale, 95% CI 0.1 to 1.6).

Conclusion

Similar long-term clinical outcomes and long-term exercise adherence are achieved with the two approaches examined in this study. Participation in gym-based group exercise may improve mental health outcomes slightly more, although the mechanisms for this are unclear because there was no change in our selected measure of social isolation or other measures of health and wellbeing. This finding may also be a Type 1 error. Further research to reproduce our results and that investigates the economic efficiency of these models of care is indicated.

Keywords

Adults, Chronic Disease, Randomised Controlled Trial, Adherence.

3.2.2 Introduction

Australian Bureau of Statistics data from 2004-05 demonstrate that approximately 70% of Australians aged >15 years were classified as sedentary or having low levels of physical activity. Physical inactivity causes a significant public health burden, with direct healthcare costs estimated at over $377 million per year in Australia.(*Australian Bureau of Statistics. Physical activity in Australia: a snapshot, 2004-05*, 2011) Chronic conditions such as coronary heart disease, stroke, depression, and type-II diabetes contribute the greatest burden to the Australian healthcare system. (Stephenson, Bauman, & Armstrong, 2000)

Greater adherence to physical activity in older adults may be one of the easiest and most effective ways to reduce healthcare costs in Australia. There are a number of interventions to enhance physical activity in populations with chronic diseases such as cardiac disease, chronic obstructive pulmonary disease (COPD), and diabetes. One such approach is to use short term (4-6 week) supervised exercise programs. Supervised exercise programs in these populations have been shown to improve clinical health outcomes, such as quality of life, anxiety, depression and exercise tolerance. (Cambach et al., 1999; Griffiths et al., 2000a; Singh et al., 1998) However, there is evidence that exercise adherence declines after the programs are completed, with many people ceasing altogether. A randomised controlled trial with 109 COPD participants identified that approximately 50% of older adults ceased exercise within 9 months of completing a supervised exercise program. (Brooks et al., 2002) Unfortunately, the benefits of exercise are rapidly lost when exercise is ceased, (Sherrington et al., 2011) highlighting the need to promote ongoing participation. Hence there is a need to identify ways to promote ongoing physical activity following completion of a short-term supervised exercise program.

Three main approaches that have been used to encourage ongoing participation: home-based exercise programs with no follow up, (Roessler & Ibsen, 2009) gym-based exercise programs, (M. K. Beauchamp et al., 2013; M. J. Berry et al., 2010; Cockram et al., 2006; Ries et al., 2003; Ringbaek et al., 2010; Spencer et al., 2010) or home-based exercise programs with telephone follow up. (Brooks et al., 2002) Home-based prescribed physical activity programs with telephone support are thought to work by embedding exercise into daily routine, and avoiding the need for travel to an exercise centre. They may fail, however, by not facilitating inter-personal connections between the individual and their peers, and by the prescriber having only limited capacity to monitor the person's physical progress. Structured gym-based programs may have an advantage over home-based programs, by controlling the amount and quality of direct training and supervision, allowing personal attention and immediate verbal feedback from the exercise facilitator. Motivation for exercise may also be enhanced via social support and interaction between exercise group members with similar health issues. (Cox et al., 2001) However, there are conflicting findings across these studies as to which of these follow-up approaches is more effective, and none have yet undertaken a head-to-head comparison in a regional suburban single site community health centre.

The aim of this study was to compare the effectiveness of a home-based exercise program with telephone follow up to a gym-based follow up program amongst adults with a variety of chronic conditions who had completed a short-term exercise program supervised by a health professional.

3.2.3 Method

Design

This was a randomised controlled trial with concealed allocation, with blinded outcome assessments conducted at baseline (ie, at the completion of the short-term supervised exercise program), and at 3, 6, 9 and 12 months. Prior to enrolment, all participants received an initial health assessment (and obtain

participant baseline demographic data) from an exercise physiologist and then completed a 6-week supervised exercise program at a community health service. This consisted of one-hour group exercise sessions, with participants encouraged to attend three sessions per week. Each participant was provided with a home-based exercise program at the conclusion of the supervised exercise program. Exercise physiologists collected baseline data for this trial at the discharge assessment of the short-term supervised program. Patients were then randomised to one of the two 12-month intervention programs. Randomisation involved the investigator opening a sealed, opaque envelope containing the random allocation sequence, which was developed by a separate investigator with no knowledge of participants' baseline results. This sequence was set out in permuted blocks of sizes 4, 6, and 8, and was stratified by the participant's primary chronic disease diagnosis type (pulmonary, musculoskeletal, diabetes, other). A blinded research assistant conducted the reassessments at 3, 6, 9 and 12 months. Participants were not blinded to group allocation, therefore their self-reported outcomes could not be considered to be blinded. However, the research assistants who administered the physical tests were blinded. This trial was registered on the Australian New Zealand Clinical Trials Register: ACTRN. ACTRN12610001035011. We received ethical clearance from The Southern Health Medical Research Ethics Committee; Number: 10187L

Participants, therapists, centres

Inclusion criteria

Participants were recruited from a pool of adults who had completed a 6-week exercise program at the Cranbourne Community Health, South East Melbourne, Australia. Those referred to this service typically have: multiple co-morbidities; poor or declining mobility; physical de-conditioning; or a combination of these problems. Mixed population rehabilitation groups are a potentially useful mechanism of service delivery for regional areas where throughput within a specific diagnostic grouping is insufficient to justify a disease specific rehabilitation program, for example, pulmonary rehabilitation.

Exclusion criteria

We excluded people with acute psychiatric impairment or cognitive impairment that made the person unsuitable for participation in a gym or home-based exercise program, as determined by health service staff. Partners and/or couples were also excluded from participation.

Intervention

Gym-based exercise program

Participants allocated to the gym-based intervention were given a 12-month, individualised, exercise program. This was supervised at the gym by an exercise physiologist from the community health service Monday to Friday for 2 hours per day. This means that there was a person present at the gym with whom the participant already had a pre-established relationship from when they had completed the initial short-term supervised exercise program. Participants were encouraged to attend during times when the exercise physiologist attended the gym. However, participants were able to attend independently during off peak times at the gym (Monday to Friday 8am - 4 pm). Each participant was encouraged to complete a one-hour exercise session, 3 times per week. They were required to pay the standard casual entry fee of $5 per visit to the gym. The exercise prescription adhered to the American College of Sports Medicine (ACSM) guidelines for chronic health conditions. (Moore et al., 2016)

The prescribed exercise included strengthening, aerobic and stretching exercise components. The strengthening component involved 40 minutes of six to eight strength training exercises for the upper and lower body (eg, leg press, calf raise, bicep curl, triceps push-down, lateral pull-down, chest press or scapula retraction) using pin-loaded resistance equipment unless contraindicated. Participants were prescribed a two-set repetition maximum per exercise set at a moderate intensity of approximately 60% of their 10

repetition maximum. The aerobic component of the exercise involved up to 15 minutes of stationary bike, treadmill or cross trainer. The rating of perceived exertion scale was used to monitor a safe “moderate” intensity. (Scherr et al., 2013)The stretching component involved 5 minutes of upper and lower limb stretching (eg, pectoral, shoulder, calf, hamstring and quadriceps) with two repetitions of each static stretch prescribed for 30 seconds. The healthcare professionals providing the intervention were trained in the Health Coaching Australia model (prescribed under their own discretion) that use motivational interviewing techniques, solution focused coaching and cognitive behavioural therapy techniques to identify techniques and address behavioural, emotional, situational and cognitive barriers to exercise adherence. (Gale, 2010)

Home-based program with telephone support

Participants allocated to the home-based intervention were also given a 12-month, individualised, exercise program. Each participant was encouraged to complete a one-hour exercise session, 3 sessions per week, at home. The home-based exercise program was supervised via 5 telephone calls over the first 10 weeks, approximately 25 to 30 minutes in duration. The total time in minutes to complete the 5 phone calls for each participant was comparable to that spent supervising each participant in the gym over a 12-month intervention period. The exercise physiologist supervising the telephone intervention was also trained in the Health Coaching Australia Model. The same exercise physiologists who provided supervision for the gym-based program also provided the supervision for the home-based program, ensuring equivalence in the experience and educational background of the providers of each of these interventions.

The exercise prescription aimed to be comparable to that of the gym-based program. It also adhered to the ACSM guidelines for chronic health conditions, (Moore et al., 2016) with strength, aerobic and stretching components comparable to the gym-based program. The strength training component involved six to eight exercises for the upper and lower body (eg, sit to stand, calf raise, bicep curl, triceps push-down, lateral pull-down, chest press or scapula retraction) using body weight or an elastic exercise band[a] to provide resistance. The aerobic component included community walking or, if participants had access to their own exercise equipment such as a stationary bike, this was incorporated.

Outcome measures

Primary outcome

Health-related quality of life was assessed using the European Quality of Life Instrument (EQ-5D). (Rabin & Charro, 2001) This questionnaire contains five multiple-choice questions and a 100-point overall health state visual analogue scale (VAS). The five questions reflect mobility, personal care, usual activities, pain/discomfort and anxiety/depression. The respondent selects one of three ordinal statements to describe their health for each. In order to obtain an overall score the Dolan utility calculator (Dolan & Roberts, 2002) was applied. A utility score is determined where 0 represents death and 1 perfect health. Test- retest reliability for community-based adults following stroke is 0.83 at 3 weeks and 0.86 at 3 months. (Dorman et al., 1998) A minimum clinically important difference using this calculation approach for the EQ-5D amongst mixed chronic diagnosis groups has been estimated to be 0.074. (Walters & Brazier, 2005)

Secondary outcomes

Productivity was measured using the Health and Labour Questionnaire. (Hakkaart-van Roijen & Bouwmans, 2007)This questionnaire contains methods for calculating productivity losses that are not the solely result of absenteeism.
Social activity was measured using the Friendship Scale, a short and user-friendly instrument that measures six dimensions contributing to social isolation and social connection. (Hawthorne, 2006) A score between 0 and 24 is obtained; higher scores indicate less social isolation.

Depression and anxiety were measured using the Hospital Anxiety and Depression Scale (HADS). (Zigmond & Snaith, 1983)The HADS includes 14 items, seven of which relate to an anxiety subscale and seven to a depression subscale. Each item is scored between 0 and 3, and a sub-scale score above 8 indicates a possible case and a score above 10 a probable case.

Body mass index (BMI) was determined by body weight in kilograms divided by height in metres squared. (Deurenberg et al., 1991) BMI has been shown to predict cardiac mortality across a 15-year span. (Oppert et al., 2002)

The 15-second sit-to-stand (STS) test (Bohannon, 1995)was included, as it is commonly used to measure lower limb strength in older people. The test–retest reliability was established to be excellent (ICC = 0.96) in a study assessing older adults with knee or hip osteoarthritis. (Lin et al., 2001) In a study examining mobility tests for predicting multiple falls in community dwelling older adults, good test–retest reliability was reported (ICC = 0.89). (Tiedemann et al., 2008)

The 6-minute walk test (6MWT), (Laboratories, 2002) which measures the distance a participant is able to walk in 6 minutes, was performed once per participant at each time point using the American Thoracic Society guidelines. In community-dwelling adults aged 65 years and older, the 6MWT showed correlations with the Short Physical Performance Battery (0.61), chair stand time (–0.62), habitual gait (0.80), maximal gait (0.80) and stair climb time (–0.83). (Mijnarends et al., 2013)

Physical activity was measured using the Phone-FITT, (Gill et al., 2008)which includes self-reported questionnaire about the frequency, intensity, time and type of physical activity undertaken. The Phone-FITT allows respondents to report on household activity (such as cooking, cleaning and gardening), recreational physical activity (such as lifting weights, playing sport physical activity), and total physical activity. A total physical activity (PA) summary score between 0 and 209 can be derived from the frequency and duration data by multiplying the two across all questions and adding the products. A higher score signifies greater participation in physical activity.

Attendance at the community-based fitness centre over the twelve months was measured via gym scanning software that recorded client attendance. Participation in alternate forms of physical activity was measured at follow-up assessments at 3, 6, 9 and 12 months, with a patient-recorded log book. Participation in home-based exercise program was measured using patient log and collated at 3, 6, 9 and 12 month assessments.

An adverse event was any injury or exacerbation of existing illness that required medical attention while participating in either intervention and was measured using the patient log book at 3, 6, 9 and 12 months.

A range of other outcomes measures relevant to an economic evaluation of this trial were also collected but will not be reported in this clinical trial report.

3.2.4 Data analysis

Each of the outcomes were compared between groups using linear regression analyses. Data were clustered within individual participants and robust (Huber-White) variance estimates were used. (H. White, 1980) Each analysis compared groups across all follow-up assessments simultaneously with adjustment for baseline scores for that same outcome. We also examined a group-by-assessment time point interaction effect to see if there was a difference in the rate of change in an outcome between groups. Alpha criterion level was set at $p = 0.05$. All analyses were conducted using Stata version 11.0.

A sample size of 52 participants per group was required for this experiment to have 90% power to detect a 7-point change in the EQ-5D visual analogue scale of global health-related quality-of-life at the 12-month follow-up assessment. Many minimal clinically important difference levels have been established for the EQ-5D VAS across a range of patient populations with chronic disease, though a 7-point change is a

standard commonly employed. (McPhail et al., 2008) A standard deviation of 11 points was used on the basis of a pre-trial survey of 20 patients within the target group conducted by the investigators. A 10% participant attrition rate was accommodated for, thus we aimed to recruit 57 participants per group into this study.

3.2.5 Results

Flow of participants, therapists, centres through the study

Participant movement through the study is illustrated in Figure 3.1.

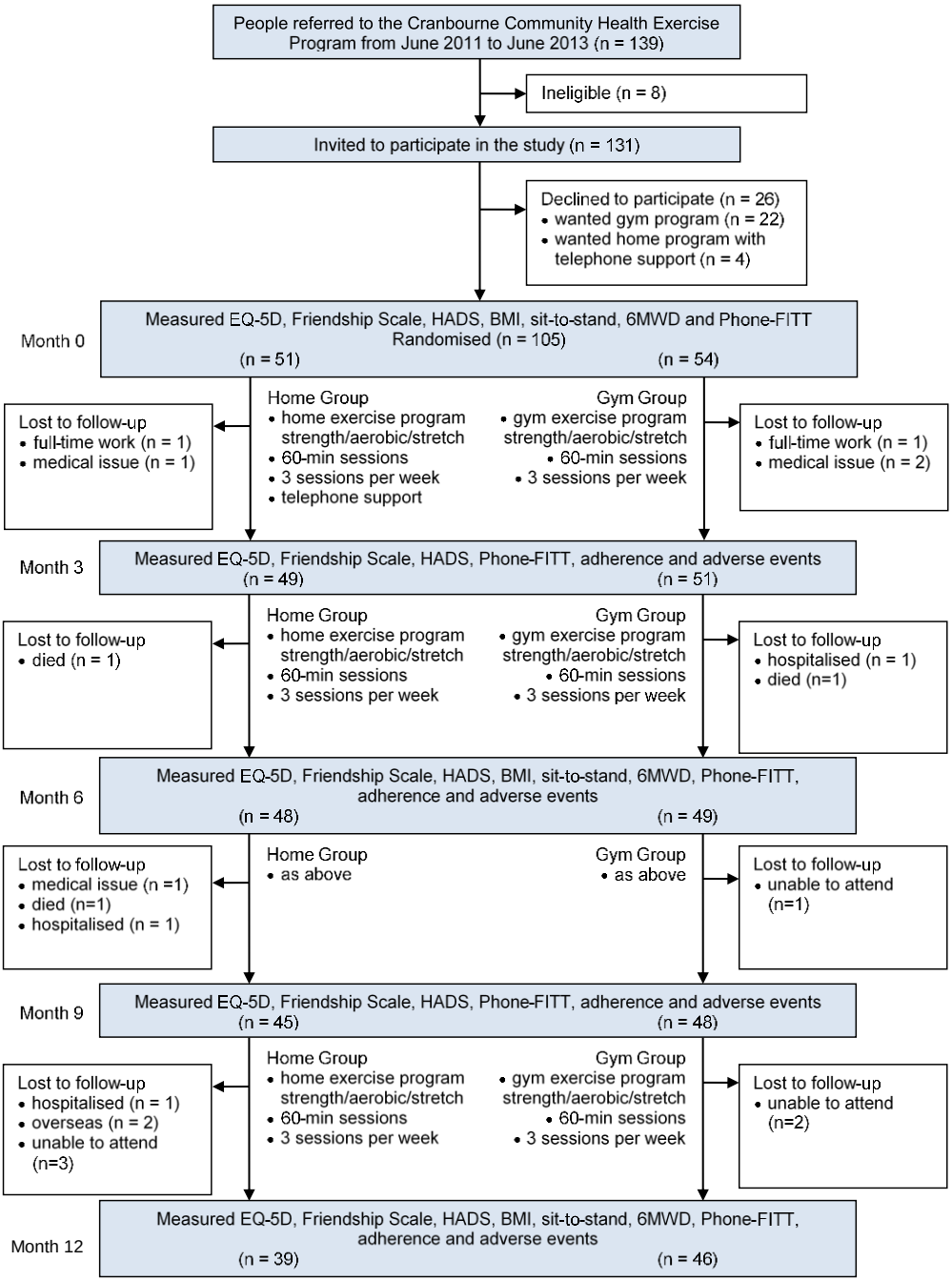

Figure 3-1 Consort Diagram flow chart of participant flow through study

Characteristics of participants

A summary of the demographics of the participants is presented in Table 3.1 and the baseline scores on the outcome measures are presented in the first two columns of Table 3.2. The two groups were broadly similar at baseline, although some discrepancies in characteristics were evident in terms of the proportion of married participants; 42/54 (78%) in gym group compared to 31/51 (61%) in the home group, and for the proportion who were widowed; 12/54 (24%) in home group compared to 2/51 (4%) in the gym group. The gym group were more likely to be born in Australia (78% vs 60%), more likely to have a primary diagnosis of cancer (39% vs 23%) or diabetes (39% vs 23%) and less likely to have lung disease (24% vs 45%).

Table 3-1 Baseline demographics and outcome measure scores for both groups.

Characteristic	Home (n = 51)	Gym (n = 54)
Age *(yr)*, mean (sd)	66 (13)	68 (11)
Gender, n female (%)	38 (75)	29 (54)
Marital status, n (%)		
married	31 (61)	42 (78)
widowed	12 (24)	2 (4)
divorced	4 (8)	7 (13)
separated	3 (6)	1 (2)
never married	1 (2)	2 (4)
Country of birth, n (%)		
Australia	31 (61)	42 (78)
United Kingdom	4 (8)	3 (6)
other	16 (31)	9 (17)
Medical conditions, n (%)		
congestive heart failure	12 (24)	12 (22)
other heart disease [a]	45 (88)	47 (87)
stroke [b]	9 (18)	12 (22)
cancer	11 (22)	6 (11)
osteoporosis or osteopenia	2 (4)	4 (7)
depression or anxiety	20 (39)	23 (43)
arthritis	20 (39)	21 (39)
diabetes	12 (24)	21 (39)
lung disease	23 (45)	13 (24)
Parkinson's disease	1 (2)	0 (0)
inner ear dysfunction [d]	2 (4)	5 (9)
cataracts	0 (0)	0 (0)
other visual impairment	11 (22)	11 (20%)
broken bone since turning 60	11 (22)	8 (15%)
joint replacement	15 (29)	18 (33)
Health service indicator, mean (SD)		
hospitalised for ≥ 1night in past 3 mo	0 (0)	7.3 (9.3)
Health insurance status, n (%)		
private health insurance	11 (22)	14 (26)
Department of Veterans' Affairs	1 (2)	3 (6)

Gym = Gym-based exercise group, Home = Home-based exercise with telephone support group.

[a] Includes coronary heart disease, cardiomyopathy, ischaemic heart disease, hypertensive heart disease, inflammatory heart disease, disease affecting one or more valves of the heart, and heart murmur.

[b] Includes stroke, mini-strokes, aneurisms, and transient-ischaemic attacks.

[c] Includes asthma, emphysema, chronic obstructive pulmonary disease, and chronic obstructive airways disease.

[d] Affecting balance, eg, dizziness

Table 3-2 Mean (SD) of groups, adjusted regression coefficient (95% CI), and group-by-time interaction coefficient (95% CI).

Outcome	Groups										Adjusted[a] regression coefficient (95% CI)	Group-by-time interaction coefficient (95% CI)
	Month 0		Month 3		Month 6		Month 9		Month 12			
	Home (n = 51)	Gym (n = 54)	Home (n = 49)	Gym (n = 51)	Home (n = 48)	Gym (n = 49)	Home (n = 45)	Gym (n = 48)	Home (n = 39)	Gym (n = 46)	Home minus Gym	Home minus Gym
EQ-5D, mean (SD)												
VAS (*0 to 100*)	70 (17)	69 (15)	64 (17)[c]	67 (18)	70 (15)[e]	70 (14)[f]	69 (18)[f]	67 (17)[d]	72 (17)	68 (17)	0 (–5 to 4)	2 (0 to 4)
Utility *(-0.594 to 1.0)*	0.67 (0.21)	0.63 (0.26)	0.65 (0.22)[c]	0.59 (0.28)	0.67 (0.25)[e]	0.67 (0.25)[f]	0.66 (0.22)[f]	0.66 (0.23)[d]	0.68 (0.22)	0.67 (0.25)	–0.00 (–0.06 to 0.06)	–0.02 (–0.05 to 0.02)
Friendship Scale *(0 to 24)*, mean (SD)	19.2 (3.9)	19.2 (4.2)	19.0 (4.4)[d]	19.2 (4.5)	19.8 (4.1)[e]	19.7 (3.4)[f]	19.1 (4.5)[f]	20.0 (3.9)[f]	17.1 (4.4)[c]	17.5 (4.2)	–0.1 (–1.0 to 0.8)	0.0 (–0.5 to 0.4)
HADS *(0 to 21)*, mean (SD)												
Depression	5.5 (2.9)	5.3 (3.3)	6.5 (3.6)[d]	5.1 (3.4)	5.5 (3.3)[e]	4.8 (3.4)[f]	5.6 (4.2)[f]	4.5 (2.9)[f]	5.7 (3.0)	4.6 (3.2)	0.8 (0.1 to 1.6)	–0.1 (–0.5 to 0.3)
Anxiety	6.5 (3.9)	5.8 (3.9)	7.0 (3.9)[d]	5.5 (4.2)	4.6 (3.8)[g]	5.8 (4.0)[f]	6.6 (3.9)[f]	4.6 (3.8)[f]	7.1 (3.9)	5.5 (4.4)	0.8 (–0.1 to 1.8)	0.1 (–0.3 to 0.5)
Body mass index *(kg/m^2)*, mean (SD)	30.7 (8.2)	32.7 (8.6)			31.0 (8.0)[h]	32.8 (8.9)[i]			31.2 (7.8)[j]	32.5 (8.3)[f]	0.3 (–0.3 to 0.9)	–0.1 (–0.5 to 0.3)
Sit-to-stand test, mean (SD) [b]	4.5 (1.5)	4.7 (1.3)			5.0 (2.3)[h]	5.3 (1.9)[i]			5.3 (1.9)[j]	5.1 (1.6)[d]	0.0 (–0.5 to 0.5)	0.2 (–0.1 to 0.6)
6-minute walk test *(m)*, mean (SD)	373 (101)	378 (99)			384 (107)[h]	400 (97)[i]			385 (127)[j]	409 (84)[f]	–12 (–35 to 12)	–5 (–18 to 8)
Phone-FITT Sum Score, mean (SD)	43 (15)	48 (13)	46 (15)[d]	45 (14)	49 (20)[e]	50 (18)[d]	46 (17)[e]	46 (14)[d]	47 (18)[c]	48 (16)[c]	2 (–2 to 6)	0 (–3 to 2)

EQ-5D = European Quality of Life Instrument, Gym = Gym-based exercise group, HADS = Hospital Anxiety & Depression Scale, Home = Home-based exercise with telephone support group.

[a] Adjusted for baseline value.

[b] Number of sit-to-stands without hand support in 15 seconds, average of two tests.

[c] One missing data point.

[d] Two missing data points.

[e] Four missing data points.

[f] Three missing data points.

[g] Six missing data points.

[h] Fourteen missing data points.

[I] Five missing data points.

[j] Seven missing data points

Effects of the interventions

A summary of the primary and secondary outcome measures is presented in Table 3.2. Regression coefficients presented represent the difference between groups averaged across the follow-up time points adjusted for baseline scores. A second coefficient is also presented representing the group-by-time interaction effect to identify whether the effect of group allocation changed over follow-up time points. There was no significant difference between study groups in the EQ-5D (primary outcome) across the 12-month follow-up. The gym group demonstrated fewer symptoms of depression (HADS - depression subscale) over the 12 months of follow-up compared to the home group with telephone follow up (p = 0.02); however, this was the only difference observed between groups.

Adherence to the interventions

The mean number of exercise sessions completed at 12-month follow-up was 52 sessions (SD 43, range 0 to 156) in the home group with telephone follow up compared to 53 sessions (SD 34, range 8 to 150) in the gym group. The proportion of people fully adherent (defined as 3 sessions completed per week) was 34% in the gym group and 33% in the home group with telephone follow up.

Adverse events

No participants reported any adverse events after completing either intervention group.

3.2.6 Discussion

This study has identified that 12-month gym-based and home-based with telephone follow up approaches produce similar longer-term outcomes in people with chronic diseases who have recently undertaken a 6-week, centre-based, supervised exercise program. The only difference in outcomes apparent was identified for the Hospital Anxiety and Depression Scale (depression subscale) outcome. We had anticipated that a gym-based program may produce superior mental health outcomes mediated via the social interaction that participants would have participated in while at the gym. However, we found no change in our measure of social isolation, bringing this hypothesis into question. It is possible that our measure of social isolation (the Friendship Scale) was not the correct scale to measure the change in the amount of social interaction a person encountered. The Lubben Social Network Scale (Lubben et al., 2006) may have been preferable for this purpose as it is a measure of social network size, rather than one of loneliness and the ability to interact with others (as is the Friendship Scale). It is possible that a mechanism of action not mediated via social interaction may also have been responsible for this finding. For example, having to go to the gym forces people to leave their house with potential mental health benefits from experiencing new environments or being exposed to sunlight while travelling to the gym. (Benedetti, Colombo, Barbini, Campori, & Smeraldi, 2001; Ng, Dodd, & Berk, 2007) It is also possible that this may have been a Type 1 statistical error, given the number of secondary outcomes examined. Overall, the mechanism for the difference in depression symptoms between groups is unclear and warrants repeated investigation to reproduce this result and to more deeply examine the potential mechanism of action. It was encouraging, however that the health states attained at the end of the initial program were largely maintained at 12 months in both groups.

To date, this study is the first to directly assess the effectiveness of gym-based follow-up compared with home-based follow-up via telephone support amongst people with chronic diseases that have just completed a supervised exercise program. A recent review has identified 11 studies that have previously examined either gym-based follow up or home-based follow up with telephone support compared to a control. Meta-regression analyses found no differential effect of follow-up approach on the rates of adherence to the exercise programs that had been prescribed. (Jansons, Haines, & O'Brien, 2016) Our study concurred with this finding in that we identified no difference in adherence rates between the two follow-

up approaches. It is still possible however, that the different approaches may have different therapeutic outcomes despite similar adherence rates. (refer to chapter 5) One could postulate that exercising in a gym environment with a range of equipment available may enhance the ability of participants to exercise at a higher intensity. Further research would be required to see if this is the case.

A limitation of our study was that we did not meet our planned sample size of 114 participants. This study was conducted in a somewhat regional suburban centre approximately 40 km from a major metropolitan city (Melbourne, Australia). The study location served as the single, major community health centre location for this area meaning that many of the current and potentially future participants in this study often interacted with each other at this centre. Consequently, study recruiters noted that potential participants were becoming increasingly aware of the study prior to being approached as the study progressed. These "study aware" individuals were forming preferences for study allocation grouping (usually centre-based) which then affected recruitment in that people who did not prefer centre-based follow-up were disproportionately refusing to enter the study. A meeting of study investigators determined that it was better to cease the recruitment early at 105 rather than recruit a biased sample into the study. A consequence of this is that our study had lower statistical power than anticipated and that we may have made Type II statistical errors. A review of the analyses of our primary and secondary outcomes indicates that this may have been an issue for the Hospital Anxiety Depression Scale – Anxiety subscale.

Our study was not able to determine whether the exercise participation rates or health outcomes would have been any better for this patient population than had a "no follow-up" control condition been employed. Reis et al (Ries et al., 2003) and Berry et al (M. J. Berry et al., 2010) found that following the completion of a short-term, supervised, pulmonary exercise program, the initial gains in 6- minute walk test distance significantly declined with "no follow up" control compared to a centre-based exercise intervention. The Short Form-36 quality of life questionnaire scores and the Fitness Arthritis and Seniors Trial functional performance inventory (Dorman et al., 1998) also significantly declined with "no follow up" control. In contrast, our 12-month follow-up indicated that health outcomes (including body mass index, 15 second sit to stand test and 6 minute walk test) were largely unchanged over this period for people allocated to either of our two follow-up approaches. One could also question whether the adherence rates observed in this study were sufficient to generate a physiological benefit for participants as both groups only participated on average one session per week. Previous research has identified that one session per week after previously completing a more intensive program is sufficient to maintain muscle strength, particularly when compared to completely stopping exercise participation. (Graves et al., 1988)

Our study had some other limitations. It was impossible to blind participants or people delivering the intervention as to group allocation. In the home-based group with telephone support, participants' self-reported adherence was recorded using log books, whereas in the gym-based group, attendance at the gym was recorded through electronic scanning of a membership card. It is anticipated that the self-report approach may be more prone to spuriously inflated scoring by study participants leading to an overestimate of exercise adherence rates in this group.

3.2.7 Conclusion

This research has implications both for clinical practice and future research. Clinicians could justifiably employ either of these follow-up approaches in clinical practice, though we would recommend use of an approach that minimises overall healthcare resource use and aligns with patient preferences. As such, future research that investigates the cost effectiveness of each follow up approach should be considered. Furthermore, there is a need to compare these approaches in this this patient population with a "no follow up" control to ensure that it is worthwhile pursuing either of these follow-up approaches. Future research could also take the form of a multi-centre trial varying location (regional vs metropolitan) to investigate whether this factor influences the relative effectiveness and economic efficiency of either approach.

4 Chapter 4- Economic Evaluation

The cost effectiveness of home-based exercise with telephone follow up compared with gym follow up amongst adults with chronic conditions that have completed a short term supervised exercise program by a health professional.

4.1 Preface for economic evaluation

The following text is adapted from an article published in 2018. Jansons, P., Robins, L., O'Brien, L., & Haines, T. Gym-based exercise was more costly compared with home-based exercise with telephone support when used as maintenance programs for adults with chronic health conditions: cost-effectiveness analysis of a randomised trial. *J Physiother*. 2018. 63 (3)154–160. doi: 10.1016/j.jphys.2017.11.010

Declaration for Thesis Chapter 4

Jansons, P., Robins, L., O'Brien, L., & Haines, T. (2018) Gym-based exercise was more costly compared with home-based exercise with telephone support when used as maintenance programs in adults with chronic health conditions: Trial-based comparative cost effectiveness. J Physiother. 2018.64 (1) 48-54 doi: 10.1016/j.jphys.2017.11.010

Monash University

Declaration by candidate

In the case of Chapter 4, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication.	80%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**	**Extent of contribution (%) for student co-authors only**
Terry Haines	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	10%
Lisa O'Brien	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	5%
Lauren Robins	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	5%

Candidate's Signature	[redacted]	**Date** 24/4/18

Declaration by co-authors

The undersigned hereby certify that:

(1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(4) there are no other authors of the publication according to these criteria;
(5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	Allied Health Research Unit, Kingston Centre, Warrigal Rd, Cheltenham 3192

4.2 Economic Evaluation

4.2.1 Abstract

Research aim

To investigate the comparative cost effectiveness of gym-based maintenance exercise program versus a home-based maintenance program with telephone support for adults with chronic health conditions who had previously completed a short term, supervised group exercise program.

Design

We conducted a randomised controlled trial with blinded outcome assessment at baseline and at 3, 6, 9 and 12 months The economic evaluation took the form of a trial-based, comparative, incremental cost-utility analysis undertaken from the societal perspective with a 12 month time horizon.

Participants

The participants were recruited following a 6-week exercise program at a Cranbourne Community Health. Refer to chapter 2 for recruitment and other participant details.

Interventions

One group of participants received a gym-based exercise program and health coaching for 12 months. The other group received a home-based exercise program and health coaching for 12 months with telephone follow-up for the first 10 weeks.

Outcome measures

Healthcare costs were collected from government databases and participant self-report, productivity costs from self-report, and health utility was measured using the EQ-5D-3L.

Results

Of the 105 participants included in this trial, 100 provided sufficient cost and utility measurements to enable inclusion in the economic analyses. The gym-based follow-up would cost an additional $491,572 AUD from the societal perspective to gain one quality adjusted life year or one year in perfect health gained compared to the home-based approach with telephone follow up. There was considerable uncertainty in this finding in that there was a 37% probability that the home-based approach with telephone follow up was both less costly and more effective than they gym-based approach.

Conclusion

The gym-based approach was more costly than the home-based maintenance intervention with telephone support. The uncertainty of these finding suggests that if either intervention is already established in a community setting, then the other intervention is an unlikely option to replace it in an efficient manner.

Keywords

Adults, Chronic Disease, Economic Evaluation, Adherence.

4.2.2 Introduction

Physical inactivity related chronic conditions such as coronary heart disease, type II diabetes and stroke are estimated to result in direct healthcare costs of over AUD $377 million per year in Australia.(*Australian Bureau of Statistics. Physical activity in Australia: a snapshot, 2004-05*, 2011)(Stephenson, Bauman, & Armstrong, 2000) Implementing strategies to increase physical activity in adults with chronic health conditions may be an effective way of reducing the economic impact in Australia. Short term (4-6 week) supervised interventions such as cardiac and pulmonary phase II rehabilitation programs have been shown to be effective in reducing morbidity and healthcare costs.(Griffiths et al., 2000b; Singh et al., 1998) However, there is evidence to suggest that once the program is completed, adherence to exercise declines along with the health benefits obtained.(Brooks et al., 2002) Hence there is a need to provide interventions to promote long-term exercise adherence after the completion of a short-term exercise program.

A recent review of this field identified two commonly investigated approaches to improve ongoing exercise adherence for adults with chronic health conditions; home-based exercise programs with telephone follow up and gym-based exercise programs. (Jansons et al., 2016) This review and meta-analysis found no difference in exercise adherence rates between these interventions. Furthermore, it identified no economic evaluations examining the comparative efficiency of the two approaches.

There is ongoing need to identify efficient means for promoting adherence to exercise in the long term and improve the quality of life of adults with chronic health conditions. The aim of the project was to examine the economic efficiency of home-based maintenance with telephone follow up compared with gym-based maintenance exercise amongst adults with a variety of chronic conditions who had previously completed a short-term supervised exercise program led by a health professional.

4.2.3 Method

Design

This economic evaluation was a comparative, trial-based, incremental cost-utility analysis conducted from the societal perspective. It used data collected as a part of a single-centre, two intervention arm, comparative effectiveness, randomised controlled trial with a 12-month follow-up time horizon. This trial was registered on the Australian New Zealand Clinical Trials Register: ACTRN12610001035011, and received ethical clearance from The Southern Health Medical Research Ethics Committee; Number: 10187L. A detailed description of trial design, participants, interventions, and outcomes has previously been published.(Jansons, Robins, O'brien, & Haines, 2017) A brief description of these is now provided.

Participants, therapists, centres

Participants in this trial (n=105) were recruited from a pool of adults who had completed a 6-week exercise program supervised by exercise physiologists at Cranbourne Community Health, a publicly funded Community Health Service in Melbourne, Australia.

Trial Interventions:

Participants allocated to the gym-based intervention were given a 12-month individualized gym-based exercise program and health coaching(Gale, 2010) supervised by an exercise physiologist trained in the Health Coaching Australia model from the Cranbourne Community Health. This exercise physiologist had been involved in providing the short-term, supervised exercise program conducted earlier at Cranbourne Community Health. Participants were required to pay the standard casual entry fee of $5 per visit to the gym. The home-based intervention with telephone support group were given a 12-month individualized home-based exercise program and health coaching.(Gale, 2010) The same exercise physiologist who provided the gym-based program also provided the home-based intervention. The participants' home-

based exercise program was monitored via five telephone calls over the first 10 weeks, each approximately 30 minutes in duration. The total time in minutes to complete the 5 phone calls for each participant was intended to be comparable to that spent supervising each participant in the gym over a 12-month intervention period. All participants were encouraged to complete a one hour exercise session as prescribed by the exercise physiologist, three times per week.

Outcome measures

Primary outcome

The primary outcome for the cost effectiveness analysis was Quality Adjusted Life Years lived, derived from repeated assessments every three months of health-related quality of life using the European Quality of Life Instrument (EQ-5D-3L).(Rabin & Charro, 2001) An overall utility score was obtained using the Dolan utility formula.(Dolan & Roberts, 2002)

Secondary outcomes

Health service resource use was measured using Pharmaceutical Benefits Scheme and Medicare Benefits Schedule data extracted by Medicare Australia with participants' consent.(*Medicare Australia. Medicare Benefits Schedule. Available at: http://www.medicareaustralia.gov.au/provider/medicare/mbs.jsp* 2011) Participants kept a logbook detailing direct health costs not captured within these databases. These included hospitalizations (including number of days and reason for admission), number of appointments with complementary health professionals, and purchases of over the counter medications. The Health and Labour Questionnaire captured data describing indirect costs (productivity) gains or losses.(Hakkaart-van Roijen & Bouwmans, 2007)

Data for cost and clinical outcomes were collected by a blinded research assistant using a face-to-face method at baseline, 6 months and 12 months and a telephone interview method at 3 and 9 months. Reliability of using telephone approaches for collecting the EQ-5D-3L and related outcomes in similar populations has previously been established.(McPhail et al., 2009)

Valuation of Cost

All costs were calculated in $AUD (Australian currency) using 2011 as a base year. The value of medications purchased through the Pharmaceutical Benefits Scheme were contained within this database. The value of pathology, radiology, general practitioner, allied health, nurse, specialised physicians, dentists, therapeutic and diagnostic procedures purchased through the Medical Benefits Scheme were contained within this database. The value of paid work productivity was calculated using the participants individual wage rate multiplied by 1.3 to cover employment on-costs (for sick leave and superannuation entitlements). Unpaid productivity was valued using market wage rates and on-costs for the private sector services to be employed to complete activities of daily living normally undertaken by each participant. The cost of acute day and overnight hospitalization during the intervention period was valued using the Victorian Weighted Inlier Equivalent Separation case mix funding system at 2011 using patient recall of length of stay and reason for admission as inputs. (*Department of Health. (Victoria) About casemix. Available at: http://www.health.vic.gov.au/casemix/about#wies* 2011) Other direct health costs such as complementary, over the counter medications and health practitioner costs not captured by Medicare Australia, home nursing, meals on wheels and home help were valued using local market prices.

We also included costs specific to the receipt of each intervention. The cost to the participant of completing the gym intervention was the casual gymnasium entry fee of $5 per session. The investigators included an additional $5 per session value on the transportation costs of travelling to and from the gym that the participant was likely to have encountered. There was no cost to the participant to complete the home-based exercise program. Health service costs related to provision of each intervention were valued using

local wage rates (exercise physiologist Grade 2, year 4 - equivalent to a Victorian public allied health professional with 4 years of experience) multiplied by 1.3 to cover employment oncosts.

4.2.4 Data Analysis

We conducted a comparative, incremental cost-utility analysis. The base analysis was conducted from the societal perspective. Healthcare costs over the 12-month follow-up period were summed within individual participants. Productivity measures were converted to an overall change in productivity relative to productivity at baseline using an area under the curve approach. A total cost variable was calculated for each participant by summing all costs across a 12-month time horizon for both intervention groups. All costs were compared between groups using the non-parametric rank sum test and t test (table 3.2). Health effects measured using the EQ-5D-3L were converted to quality adjusted life years gained (relative to baseline utility levels) using an area under the curve approach. Within this area under the curve approach, participants who missed follow-up appointments (25 participants, 38 assessments) had missing data imputed using a last-observation carried forward approach. There was also one participant whose measurements of direct healthcare costs was not provided due to administrative error. The study average was imputed for this participant.

The incremental cost effectiveness formula used was:

[Costs (home) – Costs (gym)] / [QALY (home) – QALY) gym)].

The difference in costs was calculated using linear regression, while the difference in QALY was also calculated using linear regression.

Uncertainty in this incremental cost-utility analysis was investigated using bootstrap resampling. We conducted 2000 replications of the analysis dataset size (n=100). These bootstrap replications were plotted on a cost-effectiveness plane and a 95% confidence ellipse was constructed.

Sensitivity analyses were conducted by changing the perspectives of the economic evaluation to be from patient and health service perspective. For the patient perspective, public subsidies for access to health services and medications were not included. For the health service perspective, patient out of pocket costs and productivity costs were not included. An alpha criterion level was set at p=0.05 for all analyses. All analyses were conducted using Stata version 11.0.

4.2.5 Results

Characteristics of participants

A summary of the sample demographics is presented in Table 4.1. Participants in the two groups appeared to be broadly similar across the outcomes collected.

Table 4-1 Baseline demographics

Characteristic	Home (n = 49)	Gym (n = 51)	Not included in data set (n = 5)
Age *(yr)*, mean (sd)	66 (13)	65 (11)	70 (11)
Gender, n female (%)	38 (78)	27 (53)	2 (40)
Marital status, n (%)			
married	29 (59)	41 (80)	3 (60)
widowed	12 (24)	2 (4)	0 (0)
divorced	4 (8)	7 (14)	0 (0)
separated	3 (6)	1 (2)	0 (0)
never married	1 (2)	2 (4)	0 (0)
Country of birth, n (%)			
Australia	30 (61)	39 (76)	4 (80)
United Kingdom	4 (8)	3 (6)	0 (0)
other	15 (31)	9 (18)	1 (20)
Medical conditions, n (%)			
congestive heart failure	11 (22)	11 (22)	2 (40)
other heart disease [a]	43 (88)	46 (90)	3 (60)
stroke [b]	8 (16)	10 (20)	3 (60)
cancer	11 (22)	6 (12)	0 (0)
osteoporosis or osteopenia	2 (4)	4 (8)	0 (0)
depression or anxiety	19 (38)	21 (41)	3 (60)
arthritis	19 (39)	20 (39)	2 (40)
diabetes	11 (22)	21 (41)	1 (20)
lung disease [c]	23 (47)	12 (24)	1 (20)
Parkinson's disease	1 (2)	0 (0)	0 (0)
inner ear dysfunction [d]	2 (4)	4 (8)	1 (20)
cataracts	0 (0)	0 (0)	0 (0)
other visual impairment	11 (22)	9 (18)	2 (40)
broken bone since turning 60	10 (20)	6 (12)	3 (60)
joint replacement	15 (31)	16 (31)	2 (40)
Health service indicator, mean (SD)			
hospitalised for ≥ 1night in past 3 mo	0 (0)	0 (0)	0 (0)
Health insurance status, n (%)			
private health insurance	11 (22)	14 (27)	0 (0)
Department of Veterans' Affairs	1 (2)	3 (6)	0 (0)

Gym = Gym-based exercise group, Home = Home-based exercise with telephone support group.

[a] Includes coronary heart disease, cardiomyopathy, ischaemic heart disease, hypertensive heart disease, inflammatory heart disease, disease affecting one or more valves of the heart, and heart murmur.

[b] Includes stroke, mini-strokes, aneurisms, and transient-ischaemic attacks.

[c] Includes asthma, emphysema, chronic obstructive pulmonary disease, and chronic obstructive airways disease.

[d] Affecting balance, eg, dizziness.

Table 4-2 Comparison of costs (AUD) at 2011 accrued over the 12 months follow up between groups.

Cost domain	Gym (n=51)	Home (n=49)	t test p value	Rank sum p value*
	Mean (sd) Median (IQR)	Mean (sd) Median (IQR)		
Medicine costs contributed by patient.	234 (127) 230 (133, 331)	207 (142) 177 (89, 329)	0.32	0.27
Net benefit medicine costs extracted by the Pharmaceutical Benefits Scheme.	2018 (2914) 1433 (735, 2397)	1474(1459) 1096 (392, 2056)	0.24	0.19
Benefit paid pathology costs	347 (394) 212 (103, 485)	364 (403) 238 (155, 512)	0.83	0.29
Pathology patient out of pocket,	20 (71) 0 (0, 0)	43 (169) 0 (0, 0)	0.37	0.54
Radiology benefit paid	382 (579) 255 (26, 475)	424 (474) 322 (135, 492)	0.70	0.10
Radiology patient out of pocket	13 (49) 0 (0, 0)	62 (188) 0 (0, 0)	0.07	0.59
General practitioner benefit paid	728 (464) 715 (355, 946)	890 (686) 757 (484, 1118)	0.17	0.25
General practitioner patient out of pocket	22 (58) 0 (0, 19)	28 (74) 0 (0, 0)	0.63	0.39
Allied health benefit paid	201 (297) 107 (0, 266)	159 (189) 106 (0, 289)	0.40	0.68
Allied health patient out of pocket	14 (59) 0 (0, 0)	7 (21) 0 (0, 0)	0.41	0.69
Nurse benefit paid	4 (8) 0 (0, 12)	3 (7) 0 (0, 0)	0.42	0.43
Nurse patient out of pocket	0 (0) 0 (0, 0)	0 (0) 0 (0, 0)	0.00	0.00
Specialised physician benefit paid	308 (413) 145 (0, 371)	336 (662) 200 (32, 389)	0.66	0.47
Specialised physician patient out of pocket	99 (169) 30 (0, 106)	181 (508) 44 (0, 179)	0.28	0.41
Dentist benefit paid	288 (959)	143 (654)	0.39	0.56

	0 (0, 0)	0 (0, 0)		
Dentist patient out of pocket	19 (117) 0 (0, 0)	6 (36) 0 (0, 0)	0.45	0.74
Therapeutic procedure benefit paid	200 (381) 0 (0, 294)	336 (714) 0 (0, 436)	0.23	0.42
Therapeutic Procedure patient out of pocket	106 (333) 0 (0, 0)	202 (608) 0 (0, 31)	0.32	0.14
Diagnostic benefit paid	52 (93) 0 (0, 58)	43 (90) 0 (0, 58)	0.64	0.37
Diagnostic patient out of pocket	3 (13) 0 (0, 0)	14 (61) 0 (0, 0)	0.20	0.40
Paid occupation	324 (1699) 0 (0, 0)	-106 (1986) 0 (0, 0)	0.25	0.71
Unpaid occupation	-370 (12295) -807 (-6855, 3428)	-922 (14286) -807 (-8216, 4637)	0.84	0.79
Hospital day admission	1080 (2657) 0 (0, 1017)	631 (1393) 0 (0, 709)	0.29	0.70
Hospital overnight	2555 (6854) 0 (0, 0)	1283 (2679) 0 (0, 1373)	0.23	0.86
Complementary	687 (1757) 274 (104, 719)	263 (367) 51 (0, 487)	0.10	0.10
Nursing	7 (35) 0 (0, 0)	13 (94) 0 (0, 0)	0.65	0.60
Meal on wheels	28 (198) 0 (0, 0)	86 (447) 0 (0, 0)	0.39	0.53
Home help	189 (425) 0 (0, 0)	213 (393) 0 (0, 277)	0.77	0.40
Gym cost patient	555 (338) 540 (260, 780)			
Gym cost health service	545 (332) 530 (255, 767)			
Home cost		117 (25) 123 (123, 123)		
Total costs [a]	10655 (15450) 7675 (796, 21314)	6526 (15715) 5258 (-3053, 14250)	0.19	0.13

*non parametric rank sum test have been presented where data are not normally distributed

[a] Total costs includes the sum of all costs Pharmaceutical Benefits Scheme pathology, radiology, general practitioner, allied health, nurse, specialised physician, dentist, therapeutic procedure, diagnostic, paid occupation, unpaid occupation, hospital day, hospital overnight, complementary, nursing, meals of wheels, home help, gym costs patient, gym cost health service and telephone costs

Incremental cost effectiveness using randomized controlled trial data

The total cost of providing the gym-based follow-up approach was approximately $4000 greater per participant than the home-based approach. (Table 4.2)This was not caused predominantly by differences in the comparative cost of delivering the interventions, but appeared to be largely driven by hospital overnight costs (approximately $1200 difference per patient) being higher in the gym-based group. The difference between groups in this line item was not significant when considered in isolation, possibly given the highly skewed nature of this data (median and IQR values =$0 for both groups indicating a relatively small number of patients contributed large cost values to the overall evaluation of this outcome). The primary analysis using the societal perspective identified that we would need to spend an additional $491,572 AUD at 2011 values in order to gain one quality adjusted life year gained using the gym-based follow-up approach compared to the home-based approach with telephone follow up. Our investigation of uncertainty in this finding identified that 54% of our bootstrap replications of this data had a point estimate where the gym-based intervention was both more effective, yet more costly than the home-based intervention. There was only a 5% probability that the gym-based intervention was both more effective and less costly than the home-based intervention while there was a 37% probability that the home-based approach was both less costly and more effective than they gym-based approach. (Figure 4.1)

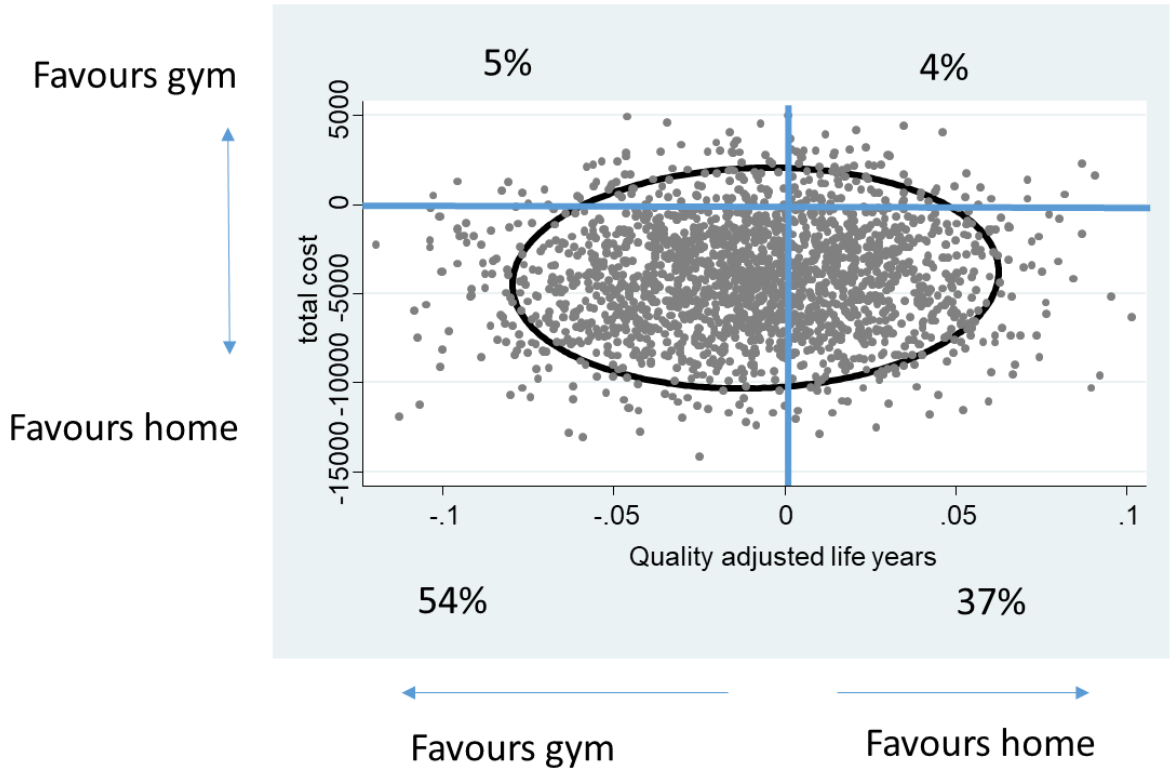

Figure 4-1 Cost effectiveness of gym based follow up versus home-based exercise program with telephone follow up with 95% confidence ellipse for Total costs versus Quality adjusted life years.

The sensitivity analysis conducted from the health service perspective identified that the gym-based intervention would cost the health service an additional $284,858 AUD at 2011 values to gain one additional quality adjusted life year compared to the home-based approach. There was similar uncertainty in this approach as compared to the primary analysis, as there was a 40% probability that the home-based approach was both less costly and more effective than the gym-based approach (Figure 4.2).

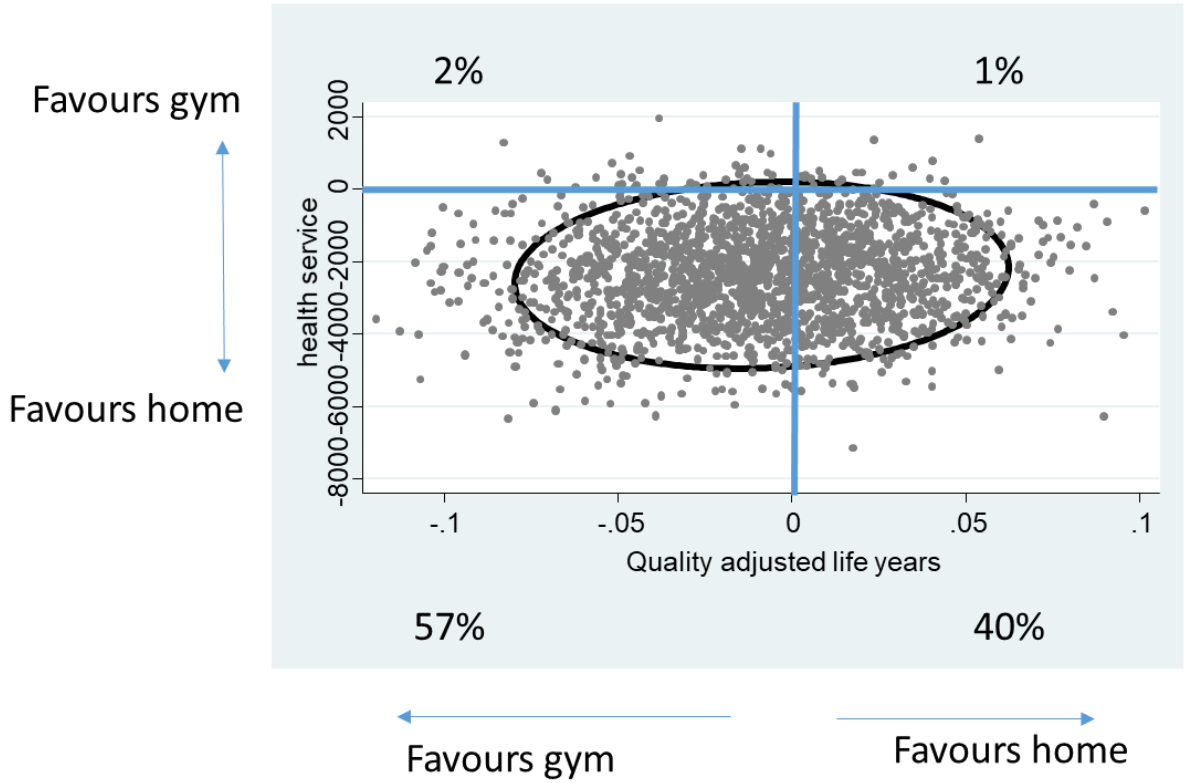

Figure 4-2 Cost effectiveness of gym based follow up versus home-based exercise program with telephone follow up with 95% confidence ellipse for health service costs versus Quality adjusted life years.

The sensitivity analysis conducted from the patient perspective identified that the gym-based intervention would cost patients an additional $206,714 AUD at 2011 values to gain one additional quality adjusted life year compared to the home-based approach. There was similar uncertainty in this finding as what was identified in the previous analyses, as there was a 29% probability that the home-based approach was both less costly and more effective than the gym-based approach (Figure 4.3).

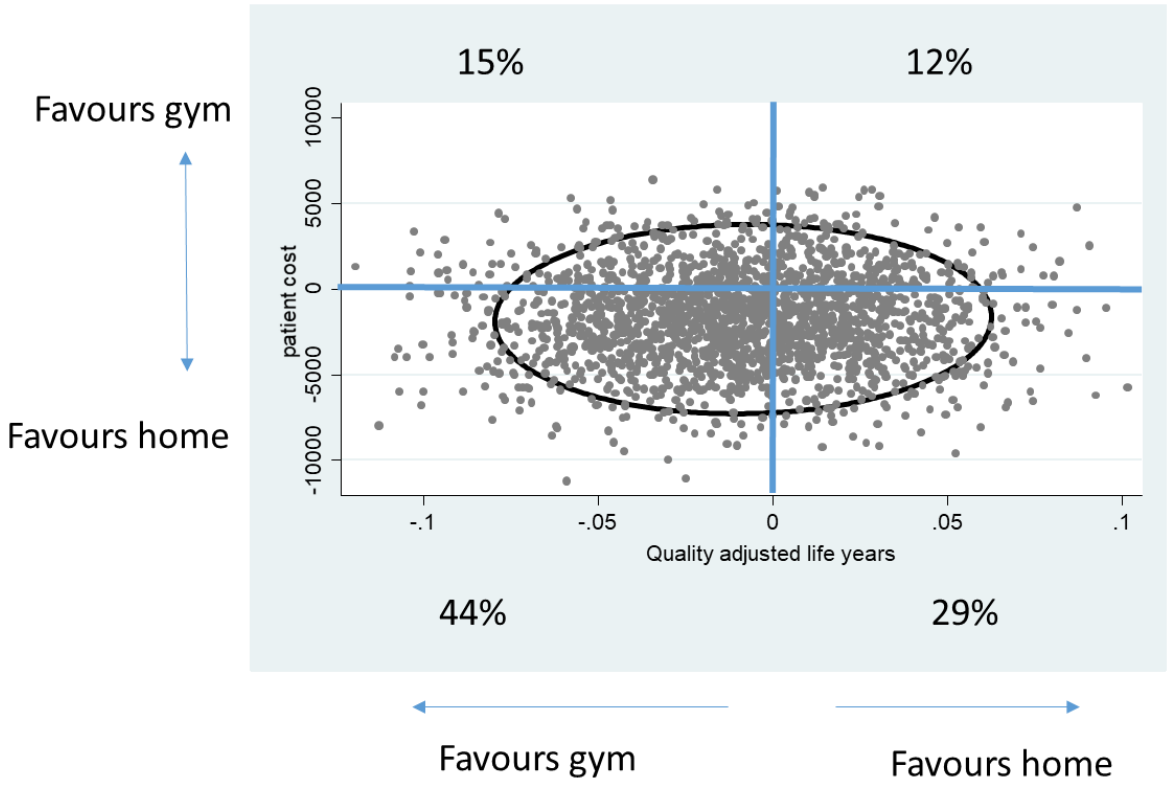

Figure 4-3 Cost effectiveness of gym based follow up versus home-based exercise program with telephone follow up with 95% confidence ellipse for patient costs versus Quality adjusted life years.

4.2.6 Discussion

Stakeholders would need to be willing to pay $491,572 for a quality adjusted life year in order to justify providing the gym-based follow-up in preference to the home-based follow-up. This value is well in excess of the National Institute for Health and Clinical Exercise(Appleby, Devlin, & Parkin, 2007) cost effectiveness threshold range of (AUD 34,200 to AUD 51,000). However, this finding should be seen in its appropriate context. The uncertainty of these finding suggests that if either intervention is already established in a community setting, then the other intervention is an unlikely option to replace it in an efficient manner. To date, no economic evaluation has been published examining the comparative efficiency of the two leading approaches for encouraging ongoing exercise adherence in people with chronic health conditions who have completed a supervised exercise program. We have identified only one trial that conducted an economic evaluation of a community gym program for people with chronic disease, however this was compared to a "no intervention" control.(Munro, Nicholl, Brazier, Davey, & Cochrane, 2004) Thus, there were few insights that could be gained in terms of likely efficiency compared to other intervention approaches that could be employed.

A limitation of this study is that our estimates of the comparative, incremental cost-utility of the interventions were highly uncertain. Factors contributing to this were the overall sample size from the randomized trial, and the highly skewed nature of some cost variables. Conducting economic evaluations alongside randomized trials can often lead to uncertain outcomes as the sample size required to address the trial primary end-point may be different to that required for the economic evaluation.(Haines et al., 2013) Healthcare costs can often be very skewed, as we observed for the "overnight hospital cost" variable in the present study. This skew in distribution also adds to the uncertainty when examining mean cost values. Another limitation was the cost difference in service delivery between the two interventions. When conducting a randomized trial, it is impossible to predict the number of patients that will be present in each

group at any point in time. This was not a problem for the home-based exercise program with telephone follow-up group where resources are consumed only on an as-required basis. However for the gym-based follow-up, the health service needed to send the exercise physiologist to the gym regardless of how many study participants were there. Hence, the same total cost was accrued regardless of whether there was one participant there or 10.

Our finding of considerable economic uncertainty along with the lack of empirical evidence of exercise adherence interventions for this patient population raises questions about the value of these programs. The primary randomised controlled trial found no difference in primary and secondary outcomes between intervention groups, except for fewer depressive symptoms in the gym follow up group.(Jansons et al., 2017) Future research needs to compare the efficiency and effectiveness with a "no follow up" control to inform clinical decision-makers which intervention is most worthwhile prescribing. Although we observe that people with chronic disease lose the gains made from participating in physical activity programs if they cease exercising, it is not clear whether strategies aimed at enhancing participation in exercise after completion of the initial program are worth pursuing. It may also be worthwhile testing these questions across different locations with varying socioeconomic backgrounds as how participants respond to these different follow-up strategies may vary on this basis.

The gym-based follow-up approach was more costly than the home-based approach, this observed difference was not driven by differential costs of intervention delivery. These additional costs are unlikely to be justified by the difference in health outcomes attained by those allocated to these approaches. Further research conducted across multiple socioeconomic groups and with an additional no-intervention comparison group is warranted to further inform clinical decision-making in this area.

4.2.7 Conclusion

Adults with a chronic disease who had completed a supervised exercise program and randomized to either a gym-based maintenance exercise program or a home-based maintenance exercise program with telephone support achieved similar outcomes a year later. To date, there is no comparative economic evaluation of the two maintenance strategies. The gym-based approach was more costly than the home based maintenance intervention with telephone support. The uncertainty of these finding suggests that if either intervention is already established in a community setting, then the other intervention is an unlikely option to replace it in an efficient manner.

5 Chapter 5-Qualitative Analysis

The qualitative analysis of home-based exercise program with telephone follow up compared with gym-based follow up amongst adults with chronic conditions that have completed a short term supervised exercise program by a health professional.

5.1 Preface for Qualitative Analysis

The following text is adapted from an article published in 2018: Jansons, P., Robins, L., Haines., T. & O'Brien., L. (2018) Barriers and enablers to ongoing exercise for people with chronic health conditions: participants' perspectives following a randomized controlled trial of two interventions. *Achieves of gerontology and geriatrics.* 2018. 76 (1) 92-99 doi: org/10.1016/j.archger.2018.02.010

Declaration for Thesis Chapter 5

Jansons, P., Robins, L., Haines., T. & O'Brien., L. (2018) Barriers and enablers to ongoing exercise for people with chronic health conditions: participants' perspectives following a randomized controlled trial of two interventions. Achieves of gerontology and geriatrics. 2018. 76 (1) 92-99 doi: org/10.1016/j.archger.2018.02.010

Monash University

Declaration by candidate

In the case of Chapter 5, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication.	80%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**	**Extent of contribution (%) for student co-authors only**
Terry Haines	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	5%
Lisa O'Brien	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	10%
Lauren Robins	Contributed to the conception of the study, undertook data analysis, assisted in the drafting of the manuscript	5%

Candidate's Signature	[redacted]	**Date** 24/4/18

Declaration by co-authors

The undersigned hereby certify that:

(1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(4) there are no other authors of the publication according to these criteria;
(5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	Allied Health Research Unit, Kingston Centre, Warrigal Rd, Cheltenham 3192

Signature 1	[redacted]	Lisa O'Brien	**Date** 24/4/18
Signature 2		Terry Haines	24/4/18
		Lauren Robins	24/4/18

5.2 Qualitative Analysis

5.2.1 Abstract

Background

At present there is no clear evidence to support any one particular intervention for engaging adults with chronic health issues in ongoing exercise. An understanding of consumer perceptions and preferences is important, because low rates of exercise adherence are likely to limit any benefits obtained**.**

Research aim

To identify and compare participants' perceptions about their own motivation, capacity and opportunity to adhere to an allocated exercise program during either a gym-based or a home-based exercise program with telephone follow-up.

Method/Design

This qualitative study used convenience sampling to recruit participants (adults with chronic health issues) immediately after a randomised controlled trial comparing gym-and home-based exercise programs conducted for 12 months. (Refer to Chapter 3) Ten people, five from each intervention group, attended face–to- face semi-structured interviews at a local Community Health Service. Thematic analysis methods were used to analyse the dataset.

Results

Improved social interaction in the gym-based program was seen to contribute to adherence, however home-based programs were perceived as more convenient and easily integrated into daily routines. Individualized exercise prescription by a health professional with regular follow up (in person or by telephone) promoted an active practitioner-participant relationship. Health coaching combined with exercise was perceived to improve self-efficacy and assisted with the removal of intrinsic and extrinsic exercise barriers.

Conclusion

This research presented many common and different themes in participant's motivation, capacity and opportunity in sustained adherence to a gym or home-based exercise program. However, this study found no superior intervention or individual preference to improve ongoing exercise adherence.

Keywords

Adults, Chronic Disease, Qualitative Analysis, Adherence.

5.2.2 Introduction

Engagement in regular physical activity is a critical component in preventing and managing chronic health conditions including cardiovascular disease, cancer, diabetes and obesity.(Stephenson, Bauman, & Armstrong, 2000) Supervised exercise programs such as pulmonary or cardiac rehabilitation programs lasting for 4-6 weeks can be effective ways for participants to commence or resume exercise in a safe and controlled environment. These programs have demonstrated effectiveness in reducing the risk of myocardial infarctions, lowering glycated haemoglobin in diabetics and reducing body mass index.(Castaneda et al., 2002; Maiorana et al., 2002) However, adherence rates decline or cease after the completion of the program, along with the clinical gains obtained,(Hughes et al., 2010) highlighting the need for effective maintenance strategies.

A recent review found two main interventions for enhancing adherence to exercise following completion of supervised exercise programs in adults with chronic health conditions: gym-based programs and home based programs with telephone follow up.(Jansons et al., 2016) Meta-analysis found no difference in the proportion of participants who were fully or partially adherent at 12 months between intervention types. A comparative study found themes in the adoption phase of their gym-based group, which primarily revolved around improved social interaction, whereas the convenience of a home-based program allowed easy integration into participants' daily routine as it eliminated transport and access barriers. This study no individual preference to improve exercise adherence in the adoption phase of either exercise intervention. (Freene, Waddington, Chesworth, Davey, & Cochrane, 2014)

The authors identified the need for comparative qualitative studies to identify the determinants of adherence to sustained exercise participation. There are many potential factors that could explain variations in exercise adherence in this population, including opportunity factors external to the individual as well as the individual's own psychological and physical capacity to engage in physical activity. Interventions that address one or more of these factors could influence ongoing exercise adherence, (Michie, van Stralen, & West, 2011) however, these factors have not been studied using qualitative methods concurrent with a prospective comparative trial.

5.2.3 Research aim

The aim was to identify and compare participants' perceptions about their own motivation, capacity and opportunity to adhere to an allocated exercise program during either a gym-based or a home-based exercise program with telephone follow-up.

5.2.4 Materials and Method

Design

This qualitative study used face-to-face semi-structured interviews and thematic analysis methods(Pope, Ziebland, & Mays, 2000) to analyse the data.

Procedure:

A convenience sample of participants, at the completion of either a 12-month gym-based exercise intervention or a home-based exercise intervention, were invited to participate. Participants were approached during their final data collection appointment. Written informed consent was obtained from the participant directly. Recruitment ceased when data saturation had been achieved.

Two research assistants with experience in qualitative research conducted the semi-structured interviews face to face at Cranbourne Community Health. A list of flexible questions were designed to elicit responses around participant's motivation, capacity and opportunity to adhere to sustained participation in either

intervention (appendix C). Research assistants were also encouraged to ask any further questions that might clarify or provide further information based on participant responses. The interviews approximately 60 minutes in duration were conducted concurrent with the final 12 month blinded outcome assessment for the exercise intervention trial. All interviews were digitally voice recorded and were transcribed verbatim by one of the research team members.

5.2.5 Participants and setting:

Participants were 10 adults, five from each intervention group. There were no participants who refused to participate in the interviews. Groups were similar in most demographic characteristics, although the home-based group were less likely to be born in Australia (60% vs 80%), and more likely to have a primary diagnosis of congestive heart failure, arthritis, or anxiety/depression (see Table 5.1). Both groups included people who were fully adherent (defined as three sessions completed per week) and people who were infrequent exercisers (defined as two or less sessions per week). There were no participants who had ceased their exercise program altogether. In the primary randomised controlled trial (N=105), the proportion of people fully adherent was 34% in the gym group compared to 33% in the home group, infrequent exerciser was 51% in the gym group compared to 43% in the home group and ceased their exercise program was 15% in the gym group compared to 24% in the home group.(Jansons et al., 2017)

Table 5-1 Baseline demographics and outcome measure scores for both groups

	Gym-based follow up	Home-based follow up
N	5	5
Age – mean (sd)	65.2 (14.37)	66.4 (12.01)
Gender (female) – n (%)	4 (80%)	4 (80%)
Marital status – n (%)		
Married	4 (80%)	3 (60%)
Widowed	0	1 (20%)
Divorced	1 (20%)	0
Separated	0	1 (20%)
Country of birth – n (%)		
Australia	4 (80%)	3 (60%)
Other	1 (20%)	2 (40%)
Medical conditions – n (%)		
Congestive heart failure	0	2 (40%)
Another form of heart disease (includes coronary heart disease, cardiomyopathy,	5 (100%)	5 (100%)
ischaemic heart disease, hypertensive heart disease, inflammatory heart disease,	1 (20%)	2 (40%)
disease affecting one or more valves of the heart, heart murmer)	1 (20%)	2 (40%)
Depression or anxiety	1 (20%)	1 (20%)
Arthritis	1 (20%)	1 (20%)
Diabetes	3 (60%)	3 (60%)
Other visual impairment		
Joint replacement		
Health insurance status – n (%)		
Private health insurance	2 (40%)	2 (40%)
Department of Veteran's Affairs	1 (20%)	1 (20%)

Trial Interventions:

The gym-based intervention group had received a 12-month individualized gym-based exercise program and health coaching supervised by an exercise physiologist from the community health service. The home-based follow up group had received a 12-month individualized home exercise program with telephone follow and health coaching also supervised by the same exercise physiologists from the community health service. The exercise physiologists providing both interventions were trained in the Health Coaching Australia Model that use techniques such as motivational interviewing and cognitive behavioural therapy techniques to identify barriers and enablers to ongoing exercise adherence.(Gale, 2010) All participants were encouraged by their health professional to complete a one hour exercise session as prescribed by the exercise physiologist, three times per week. A detailed description of the elements specific to each intervention has been described previously.(Jansons et al., 2017) Refer to Chapter 3.

Ethical consideration:

This study received ethical clearance from The Southern Health Medical Research Ethics Committee; Number: 10187L.

5.2.6 Data analysis

A thematic framework was used to analyse the data.(Pope et al., 2000) NVivo computer software (version 11, QSR International Pty Ltd, Doncaster, Victoria, Australia) was used to code, chart and map the data. Five stages of coding were completed: i) Familiarisation; ii) Identifying a thematic framework; iii) Indexing; iv) Charting; and v) Mapping and Interpretation. The epistemological view that has been taken during this qualitative study was intrepretivism, the ontological stance was realism. (Pope et al., 2000)

An iterative process was then used to test and retest the thematic framework. Data were analyzed both within and between the two intervention groups. Two authors (PJ) and (LOB) then compared content and themes. Any disagreement was resolved by consensus moderation.

5.2.7 Results

Common themes across both intervention groups

Figure 5.1 depicts intrinsic and extrinsic barriers and enablers of ongoing exercise participation that were common to both intervention groups.

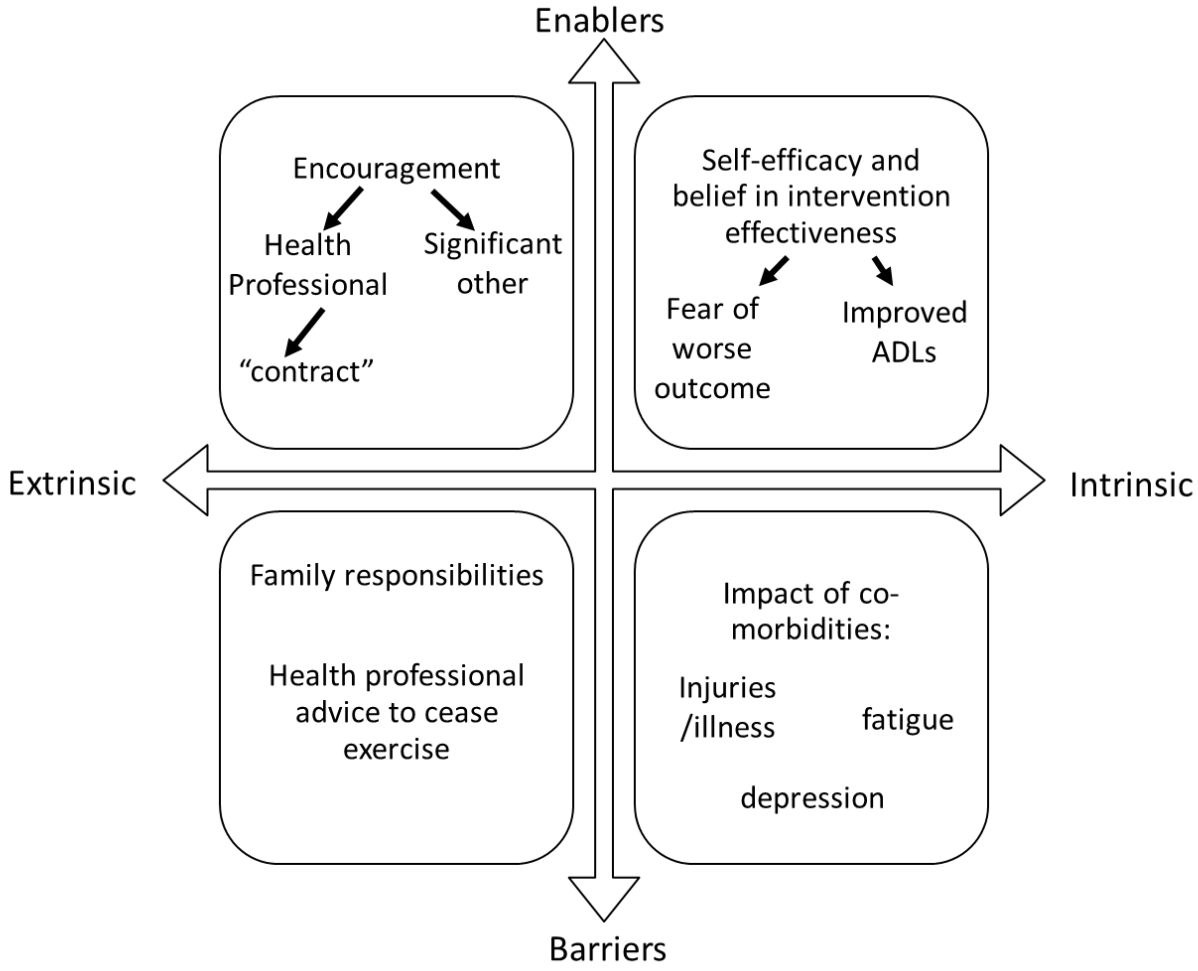

Figure 5-1 Intrinsic and extrinsic barriers and enablers of ongoing exercise participation that were common to both intervention groups

Key external enabler: Encouragement from significant others or the health professional

Encouragement and support from either family and friends or health professionals was found to be a primary motivator amongst participants in both intervention groups.

"*There is only the wife at home and she was very encouraging with it." (Participant 1-male, home-based follow up)*

"It's nice to be - I don't know if the word is checked up on - but it's nice to know that you have got that back up. That you haven't just said 'go away for twelve months and do these exercises' and no one actually speaks to you and says 'how are you going?'" (Participant 1-male, home-based follow up)

"It's not like you are being checked up on, because the phone calls were never like that. It was just 'how are you going?'. … just knowing that someone was actually going to be ringing up and saying 'have you been doing your exercises?'. That puts the pressure on to do them." (Participant 4-female, home-based follow up)

Some participants identified their own low motivation to exercise, and need for external support.

"You tend to say to yourself 'at my age what is the point?' and that's when you chuck it in. You really need someone to push you and get you going." (Participant 3-male, gym-based follow up)

Furthermore, some participants established a "contract" with the health professional and this motivated them to keep going.

"*I was assigned to do the exercises (in the gym). That it is not quite binding, but it is. You are in a contract really when you think about it." (Participant 2-female, gym based follow up)*

Key internal enabler: Self-efficacy and belief in intervention efficacy

Motivation in the form of participant's self-efficacy or belief in a positive effect after completing the exercises was commonly reported.

"It's a bit like dieting, you either do it or you don't do it. It's just a decision you have to make. You can't have someone say to you, 'do this' or 'do that'. You have got to decide to do it yourself. Sometimes it's a bit hard. But you persevere and you can see the benefits from it." (Participant 1-male, home-based follow up)

"If you don't do them, you've got that little voice in your head saying 'you didn't do the exercises today'…(so) I would try to fit them in the next day." (Participant 4-female, home-based follow up)

"Well I know it is helping. Slowly, but it is helping. And I know down the track it is going to have benefits. It's just that really. I'm not really an exercise person, so I don't go along to exercise. But I know it's helping me and I know I need to do it." (Participant 3-male, gym-based follow up)

"Walking for starters … I was getting very reluctant to walk anywhere. But since then I tackled quite a few things that I had given away. Walking to the local shops. Things like that. Lifting, I can lift anything now more or less to what I used to. And general fitness. And my legs have also improved to the point where I did use a stick occasionally and now I don't." (Participant 3-male, gym-based follow up)

Many participants continued to exercise with the belief that they would get worse if they did not continue to do the exercises.

"Basically … I know I need to keep on doing it. I have so many issues with my back, my hip and my legs. I'm concerned if I don't do stuff now, down the track when I'm older I'm going to have a lot more serious issues…so I want to keep moving and just stay on top of it." (Participant 2-female, gym-based follow up)

Key Internal barrier: Impact of co-morbidities

Internal barriers revolved around illness and injuries that were not related to either exercise intervention.

"Apart from if I hurt my back - not due to the exercises but something else - I just couldn't go. Or when I was sick, had the flu and couldn't go. Twice last year I couldn't go. I think I missed out five weeks during that time." (Participant 2-female, gym-based follow up)

Some participants suffered from bouts of depression, which prevented them from engaging in their activities of daily living, including their exercise program.

"*I am depressed. I feel these things make me not want to do anything." (Participant 9-female, home-based follow up)*

Other participants were only partially adherent due to their fatigue levels. *" I've got to do this and I've got to do that and if I do the exercises, I won't have the energy to do that. So, I've been a bit naughty and skipped a few of them." (Participant 5-female, home-based follow up)*

Key External barrier: Family responsibilities and health professional advice

Some participants were advised not to exercise by their health professionals due to exacerbations of their health conditions.

"*I had a few medical problems and I've been told to relax and not do too much energetic stuff. To do with my breast cancer problems." (Participant 5-female, home-based follow up)*

A commonly reported external barrier was that participants were physically unable to find time to exercise regularly due to family responsibilities such as looking after their children or grandchildren.

"(It) makes it hard to have your (disabled) son at home all the time. You are on call with him all the time. (Participant 8-female, gym-based follow up)

Different themes between the two intervention groups

It was noted during discussion between authors that key themes differed between the two exercise interventions during coding. These have been grouped into: home-based follow up enablers and barriers (Figure 5.2) and gym-based follow up enablers and barriers (Figure 5.3).

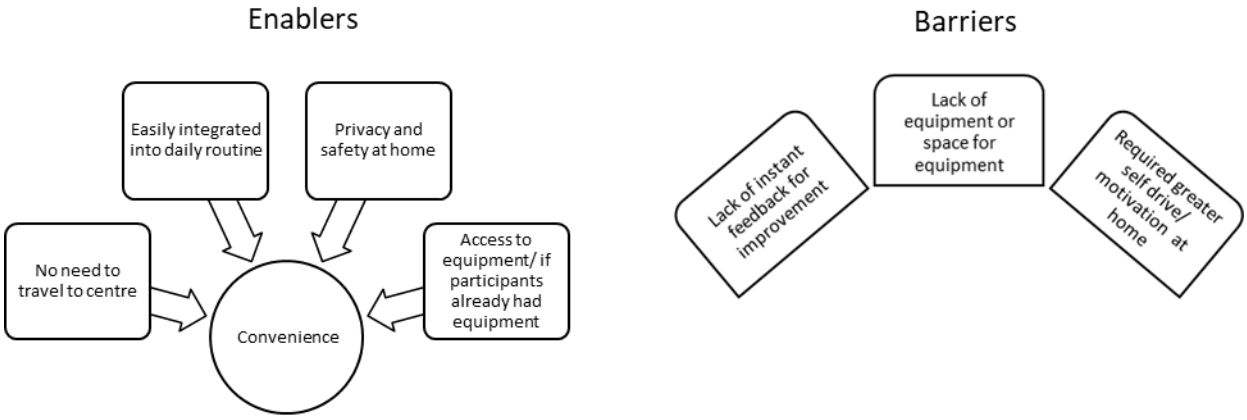

Figure 5-2 Home-based follow up enablers and barriers

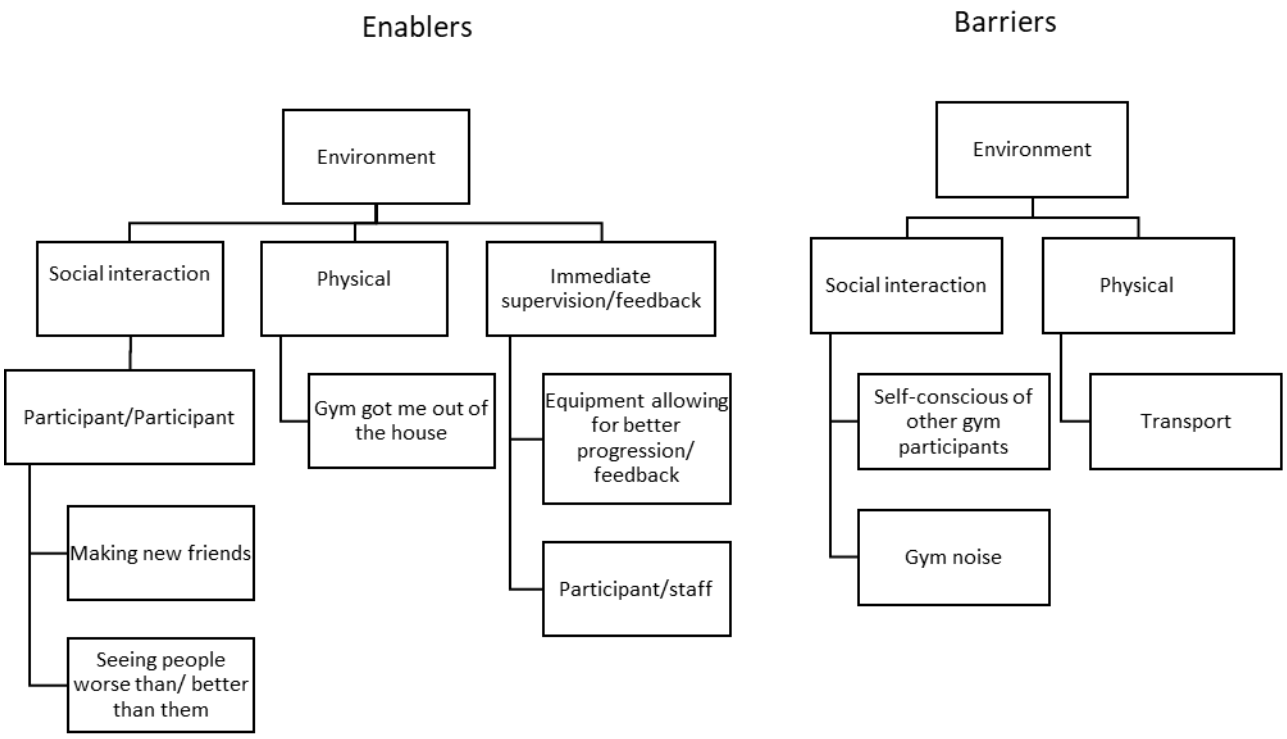

Figure 5-3 Gym-based follow up enablers and barriers

Key external enablers to home-based exercise intervention: Convenience

Convenience was a primary motivator for home-based exercise intervention participants to continue to complete their exercise program.

"Last night I was on my treadmill. I did 10 minutes … when I had some spare time. I did the rubber thingy as they were hanging on the door. Every time I see it there, I think I should do that now." (Participant 5-female, home-based follow up)

"Apart from the exercise bike, I can do everything at home. I know how to do them and what steps to use. And I've got my rope thing, so it's all there for me to do when I can. … I don't see the point in going to the gym to do it. They have got the treadmill down there (in the retirement village) which is very convenient." (Participant 5-female, home-based follow up)

Participants that were fully adherent established a routine more easily at home and integrated their exercise program into their own activities of daily living.

"I've got into the routine and that is more or less what life is about. You get into a routine of something and you just do it. I ride my bike before my breakfast and you just get in a routine." (Participant 1 male, home-based follow up)

"I think the routine of doing them. When you say to yourself 'I've done my light housework', you know you have got to do the exercises." (Participant 4-female, home-based follow up)

Completing exercises at home allowed participants the privacy to perform exercises without feeling judged or observed.

"I'm not saying people look at you, but sometimes you feel as though they are looking at you when you are doing the exercises. Whereas when you are at home, it is just you." (Participant 4-female, home-based follow up)

"You don't have to get out and get dressed up. You can lounge around in your old clothes and do it at home." (Participant 1 male, home-based follow up)

Participants exercising at home were not reliant on driving, public transport or family/ friends to transport them to a facility to exercise.

"*And it's no secret, it's not the best spot in the world to park at. So you haven't got that problem. You save yourself a 20 minute drive, plus parking and plus getting changed.". (Participant 1 male, home-based follow up)*

Key External barrier-home-based intervention: lack of equipment and instant feedback for improvement.

Participants who did not own exercise equipment (e.g. treadmill, cross trainer) or have the space to use their exercise equipment were less likely to be adherent.

"You certainly haven't got the same equipment you would have if you went to the gym obviously." (Participant 4-female, home-based follow up)

"My partner's son has moved back in a put all his tools and stuff in the garage and I couldn't get to my stuff." (Participant 1-male, home-based follow up)

Some home-based group participants had a preference for their initial centre-based group supervision and reported needing greater self-motivation to complete their exercises at home.

"(I'd) probably be a bit better at the gym than being at home. Sometimes you slack off a bit, where(as) at the gym you feel that someone is there and looking at you. What are you doing (or if you're) not doing it properly. That's all, I think home is pretty good but you would be more dedicated at the gym because you think that you have to do it right." (Participant 5-female, home-based follow up)

Some participants preferred the instant feedback and external motivation that they received in the initial supervised centre-based program.

"Sometimes you tend to slack off a bit. You've got to motivate yourself…… you do it at home and you think to yourself, 'well I don't think I feel like doing it today.' You've got to make that commitment. When I was coming up to the gym (pre-trial supervised centre-based program) I was committed, so I had to do it. (Participant 1-male, home-based follow up)

"Harder is the motivation. If you are not feeling 100 percent on the day and you have got your exercises to do, it is easier to say 'I'm not going to do it'. It's easier when someone is there saying to you 'come on, do 10 minutes.'" (Participant 1-male, home-based follow up)

Key external enablers for the gym-based exercise intervention: social interaction and change of environment

Participants reported a number of motivating factors that contributed to their adherence to the gym-based intervention, these were grouped into the categories of 'social', 'physical' and 'feedback'. The gym-based intervention introduced an element of social interaction amongst both trial based and general gym-based participants. Many participants only chose to attend during times when they knew they could interact with their 'new' friends. Some even self-initiated peer support networks outside the gym-based setting which further established a new social network.

"We used to get together once a month and catch up for coffee." (Participant 7-female, gym-based follow up)

"I know quite a few people that go there now and we talk or sit next to each other and ride the bike together or row the machine." (Participant 3-male, gym-based follow up)

Social interactions with participants they perceived as having worse health than themselves provided a role-model and encouraged greater self-motivation.

"You come here and you see people, very elderly people, and they are having a go. They are trying. You see that very old lady, a little tiny thing. To think that this is a lady that is going to embark on the same thing. It's marvellous, I think." (Participant 3-male, gym-based follow up)

"*Most people don't even know about it. Most people wouldn't even have a clue. They know about all the different gyms and that and they say 'that's for the kids'. They don't realise it for them as well. It wakes you up." (Participant 3-male, gym-based follow up)*

"You meet different people and see the different people. You see people that (have) properly got problems and you think to yourself 'what am I whinging about? They would swap with me happily". (Participant 7-female, gym-based follow up)

Completing exercise at a location removed from the participants' own homes had associated motivational benefits

"The thing is I don't particularly like exercising, so the fact that I had to go there, that I was joined up, that was my motivation. Because if I was left to do it at home, I would just not do it. So the fact that I had to get up, and go out was a motivating factor for me. You've got to do this, you have to do at least twice a week and that pushes me." (Participant 2-female, gym-based follow up)

"There was no way known I would have got out of bed and done the exercises like I do now. I have become a (gym)junkie." (Participant 3-male, gym-based follow up)

"As I said, that fact that I was joined up there and I have to go; that motivates you. When you are at home, I fiddle around at home and what-not …. If you have to do it at home you tend to think you can do it later when you get this done and you never get around to it. So I don't think I would have gone very well (if I received the home-based program)." (Participant 2-female, gym-based follow up)

Proximity to home was important for attendance.

"It was just easy because it is local… You just walk in, and just do your thing and there are no hassles. It is easy." (Participant 7-female, gym-based follow up)

Gym equipment provided feedback that encouraged goal-setting to obtain further physical improvements.

" The rowing machine, I liked that because it occupies most of your muscles. I usually do five minutes on the top level. And the knee press. That was a bit of a challenge but I persisted with it and it came good. And the pulldowns, that sort of stuff. And the weights, I progressed to a 5 kg weight in the wrist curl." (Participant 3-male, gym-based follow up)

Gym-based health professional supervision was perceived to improve adherence by contributing to accountability, exercise progression and safety

"Well if I did them wrong I would be corrected by one of the physios. They watch you. You don't think they are but they are."(Participant 3-male, gym-based follow up)

"You have to look over your shoulder to make sure if you do something easy. You make sure they are not watching." (Participant 3-male, gym-based follow up)

"I think it was being in company, rather than being isolated and doing it on your own. I think the constant attention from the physio on duty, from the integrated care services was greatly appreciated. It's true. Without them there, you tend to skive off or stand talking. It's true, you can see it quite often. People look over their shoulders, see where the physio is and have a bit of a blow (rest)." (Participant 3-male, gym-based follow up)

"And knowing that they were there, I wanted them to see that I was participating, that I was coming. Because I didn't want them to think, 'oh I haven't seen (participant) for a while.' That sort of thing. I wanted them to know that I was committed to it and that they were seeing me there." (Participant 2-female, gym-based follow up)

Key external barriers gym-based intervention: Environment and Transport

Barriers to adherence included negative physical and social aspects of participating in a local gym.

"The lady that runs the bicycle group shouts at the top of her voice and has music loud and that's the only compliant I have. I don't mind watching the girls do their aerobics, that is fine. But when she is screaming out at the top of her voice, it is unbelievable. I'm deaf and I take my hearing aid out and put ear plugs in!" (Participant 3-male, gym-based follow up)

Being self-conscious and feeling intimidated by other gym-based members prevented full adherence for some female participants.

"I guess the only thing I didn't like was down the back room. You get a lot of regular gym members down there, at certain times. And they would be using something that you wanted to use. When I started, I thought it was specifically for (our intervention group). And there would be guys down there and I feel really funny exercising in front of guys. So sometimes I felt, maybe I would give it a miss or I would leave an exercise if there was a guy sitting on it. I would then just go home. He was there and he was doing it, and I'm not going to wait around. So that was probably the only down thing to it. I just thought it was specifically for this program and there wouldn't be other regular gym users in there. They would come in with their water bottles and do some exercises and they would just sit there and I would feel funny doing my balance exercises and I would want to use that machine. So that was the only down thing." (Participant 2-female, gym-based follow up)

Transport and access issues prevented frequent attendance.

"It seemed every time I had the chance to go to the gym (the partner) would take the car or it didn't work. Here we go again. Sorry" (Participant 7-female, gym-based follow up)

"It just seemed fate that every time I tried to do it. 'Sorry you can't get there. I need to take the car.' " (Participant 8-female, gym-based follow up)

5.2.8 Discussion

This research identified many common and contrasting themes in participant's motivation, capacity and opportunity to adhere to ongoing exercise. To our knowledge, this study is the first to complete a qualitative analysis of participant perceptions of the maintenance phase (i.e *after* completion of a supervised 4-6 week program) of gym-based and home-based exercise programs amongst people with chronic diseases. The themes that we identified were largely concordant with previous work examining factors affecting participation in similar populations during the earlier adoption phase of exercise programs.(Freene, Waddington, Chesworth, Davey, & Cochrane, 2014) An important perspective apparent in this research that may be more particular to the maintenance phase was the realization by participants that their physical activity behaviors needed to change forever, and the need for persistence once the initial novelty of regular exercise had worn off.

Encouragement from a health professional by prescribing an individualised exercise program using goal setting with regular contact was commonly mentioned by trial participants to help facilitate adherence to either intervention. A number of studies have established the effective use of goal setting in the adoption phase of an exercise program (Bassett & Petrie, 1999; Evans & Hardy, 2002; Ziegelmann, Lippke, & Schwarzer, 2006), however, there is limited evidence demonstrating its effectiveness in maintaining

exercise adherence. A study by Bassett et al of sixty-six physiotherapy participants with a mean age of 41 and diagnosed with a limb injury (in the adoption phase of a supervised exercise program) found that exercise adherence was superior when treatment goals were “collaboratively” set when compared to physiotherapist-mandated goals.(Bassett & Petrie, 1999)

Interpersonal relationship i.e a health professionals expected experience in treating chronic conditions and trust has been found to improve adherence to an exercise program three fold when compared to a non-health professional.(Safran et al., 1998) However, the frequency of health professional contact may be more important during the maintenance phase of an exercise program. A recent meta-analysis hypothesised that an increase in health professional contact would correlate with an increase in exercise adherence, however, a meta-regression analysing this relationship was not conducted.(Jansons et al., 2016) Our randomised controlled trial found similar adherence and clinical gains between the two intervention groups independent on the amount of health professional contact.(Jansons et al., 2017) Further research comparing these two follow up approaches with a “no follow up” control maybe warranted.

Participants in our study whose comments suggested higher self-efficacy regarding exercise were more adherent regardless of intervention group. It is thought that participants with higher self-efficacy in the adoption phase of an exercise program have a greater ability to overcome barriers and prevent relapses.(Dunlop & Beauchamp, 2013) However, there is limited evidence regarding the role of self-efficacy in the maintenance phase of an exercise intervention. A pre-post study of pulmonary rehabilitation participants that were recruited into a maintenance intervention (weekly respiratory nurse telephone calls and two physiotherapist home visits) found that higher self-efficacy ratings as measured by the COPD Self-Efficacy Scale were associated with better quality of life and adherence rates. (Cooke, Moyle, Griffiths, & Shields, 2009) Our study did not include a measure of self-efficacy, however, it seems that role of self-efficacy is equally important throughout adoption and maintenance phases of exercise programs.

Unavoidable illness and injuries not related to either intervention was identified as a major barrier to participation in our study. This included bouts of anxiety and depression. This is consistent with a randomised controlled trial of pulmonary disease participants (N=59) which compared centre- and home-based exercise interventions over 12 months. This study found that participants that had no detected anxiety (an anxiety score on the 7 or lower) as measured by the hospital anxiety depression scale were more adherent to their intervention exercise program.(Spencer et al., 2010) There is evidence to suggest that health professionals should screen for anxiety and/or depression using validated tools and, if indicated, refer to relevant heath care services in order to enable greater participation levels. Educating patients about the important role of physical activity in managing mental health issues or illness has been proven to improve adherence.(Lim, Moon, & Lee, 2005)

Our finding of a link between adherence and greater social interaction amongst the gym-based group contrasts with that from another study comparing gym-based follow up with home-based follow up for type II diabetics.(Dunstan et al., 2006) Researchers in that study found the majority of participants chose to exercise outside supervised sessions and instead aimed to improve social interaction by allocating participants to buddy or ‘peer group’ sessions. Our findings might be explained by participants forming their own informal ‘peer support’ networks outside the gym. This provided motivation or incentive to leave their house to interact with the ‘new friends’ in a new environment. There is evidence that peer support and role modelling can provide a sense of belonging to social network of like-minded people in the initial adoption phase of an exercise program. A qualitative study of an all-male (n=19, mean age 77.1) supervised exercise program identified themes of social connectedness and demographic homogeneity to be major enablers of attendance at a weekly supervised exercise program.(Dunlop & Beauchamp, 2013)

Another form of role modelling for participants in the gym-based intervention group was the empowering effect of seeing people participate who they perceived had worse health than themselves. Social or interpersonal comparisons may have allowed gym-based attendees to more accurately evaluate and

compare their own physical abilities, reduce uncertainty and appropriately define or normalise their own chronic health conditions. A literature review of 21 studies examining the social comparison theory in adults with chronic illnesses found positive or negative comparison is dependent on the participants' ability to cope with their own medical condition regardless of how good or severe the comparable condition is.(Arigo, 2012) Therefore the role-modelling in gym-based therapy to normalise their own chronic conditions may further assist adherence.

Immediate feedback or progression through the use of gym equipment may have enhanced ongoing exercise adherence. A trial postulated that gym attendees with Type-II diabetes improved their glycemic control as they had access to familiar exercise equipment from their initial centre-based supervised exercise program, compared to a home-based follow up group who used improvised or unfamiliar equipment.(Dunstan et al., 2006) Gym-based participants also had access to a greater range of equipment, enabling exercise to be completed at a higher intensity. The equipment providing feedback that encouraged goal-setting to obtain further physical improvements, for example progressively increasing the resistance in a pin loaded leg press, may have also reinforced their motivation to continue to exercise.

There is evidence to support our finding that some older adults with chronic health conditions prefer to exercise at home for reasons of convenience, privacy, incorporation into daily routines, and diminished access to transport. A randomized controlled trial (N=109) comparing similar interventions for people following phase II supervised pulmonary rehabilitation programs concluded that home exercise programs that were easily integrated into daily routine (e.g. walking around the local area) resulted in superior adherence when compared to the strength training component in the gym-based group.(Brooks et al., 2002) A qualitative study involving sedentary middle-aged adults aged 50-65 years allocated to either gym- or home-based programs prescribed by physiotherapists found that home-based programs with telephone follow up may be more age-appropriate with similar themes emerging around flexibility, convenience and more easy integration into activities of daily living. However this study equally found no superior intervention or overall preference for a gym or home-based program to improve exercise adherence.(Freene et al., 2014)

5.2.9 Limitations

A limitation of this study was the sample size of 10 participants. Although we reached data saturation, themes may not represent the perceptions of all participants in the primary trial. A further limitation was that trustworthiness may not have been achieved as we did not conduct member-checking of the transcript and codes to ensure it was an accurate representation of their experience during either intervention.

5.2.10 Conclusion

This study found no superior intervention or individual preference to improve ongoing exercise adherence. Individualized exercise prescription by an exercise physiologist with frequent follow up seems to be effective in promoting trust, rapport and support. Providing health coaching in parallel to exercise may improve self-efficacy and assist with removing many of the intrinsic and extrinsic barriers. Enablers for those in the gym-based group primarily revolved around improved social interaction whereas the home-based program was easily integrated into participants' daily routine as it eliminated transport and access barriers. Understanding the determinants of adherence and strategies that are most effective in influencing exercise among older adults who have completed a supervised exercise program is extremely important for health professionals because low rates of exercise adherence are likely to limit any benefits obtained from short-term interventions.

6 Chapter 6 – Synthesis of main findings and conclusions

6.1 Introduction

There were three aims to this thesis. The first and second aims were to establish the comparative clinical effectiveness and cost-efficiency of gym versus home-based exercise programs with telephone follow up for adults with chronic health conditions who had previously completed a short term, supervised group exercise program. The third aim was to describe and compare participants' perceptions about their motivation, capacity and opportunity to adhere to either intervention using a qualitative design. This chapter will provide a synthesis of main findings from Chapters 1, 3, 4 and 5. In addition, this chapter will discuss the strengths, limitations and future direction of each study presented in this thesis.

6.2 Summary of main findings

The thesis reports on an extensive investigation to identify the most clinically effective and cost-efficient ongoing method to engage adults with chronic health conditions. However, the results present a clinical and societal dilemma. The systematic review (chapter 1) aimed to determine which exercise adherence interventions are most effective for achieving ongoing exercise adherence in adults with chronic health conditions after completion of a supervised short-term program. This review found no difference in the proportion of participants who were fully adherent to an exercise program at 12 months between the centre-based follow-up (pooled proportion fully adherent=0.34) and home exercise program with telephone follow-up (pooled proportion fully adherent=0.33). It must be noted, however, that most included studies were of low quality, and we identified no studies directly comparing the clinical effectiveness or efficiency of centre-based and home exercise program with telephone follow up. This warranted the investigations contained in this thesis.

The randomised controlled trial (chapter 3) found similar results in all outcomes measured, including adherence rates, between the two groups. The only difference was that participation in gym-based group exercise may result in better mental health outcomes. Therefore, an economic evaluation (chapter 4) comparing these two interventions was warranted to justify policy decisions. This analysis found that gym-based follow-up would cost an additional $491,572 AUD from the societal perspective to gain one quality adjusted life year compared to the telephone-based approach. There was considerable uncertainty in this finding in that there was a 37% probability that the telephone-based approach was both less costly and more effective than they gym-based approach. The gym-based approach was, however, costlier to implement. The uncertainty of these finding suggests that if either intervention is already established in a community setting, then the other intervention is an unlikely option to replace it in a more efficient manner. Chapter 5 presented the common and contrasting enablers and barriers that impact on participants' motivation, capacity and opportunity to sustain exercise adherence. This chapter found providing health coaching in parallel to exercise may improve self-efficacy and assist with removing many of the intrinsic and extrinsic barriers. Enablers for those in the gym-based group primarily revolved around improved social interaction whereas the home-based program was easily integrated into participants' daily routine as it eliminated transport and access barriers. However, this study found no clear preference for either exercise intervention. Clinicians could justifiably employ either of these follow-up approaches in clinical practice, depending on the individual's access to transport or equipment. If a telephone based service is already in place, then a gym-based service would be unlikely to more clinically efficient or cost-effective.

6.3 Synthesis of main findings and implications across this thesis

From this thesis it has emerged that there are several factors that influence participation in and adherence to physical activity intervention in people with chronic disease. The Physical Activity Maintenance Theory will now be used to frame the discussion of these factors.

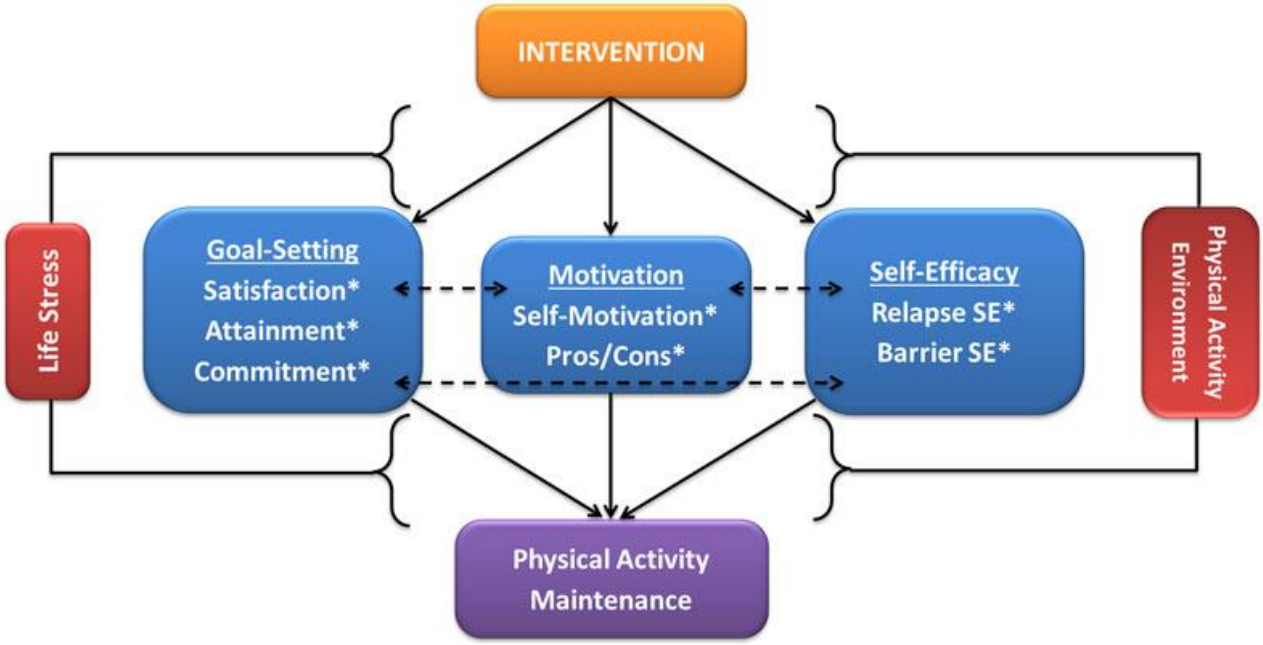

Figure 6-1 (Source: Nigg, C. R., Borrelli, B., Maddock, J., & Dishman, R. K. (2008). A theory of physical activity maintenance. Applied psychology, 57(4), 544-560.: reproduced with permission)

The Physical Activity Maintenance Theory, Figure 6.1 by Nigg et al, 2008 is the only physical activity specific behavioural change theory to date that seeks to address the determinants specific to ongoing adherence. (Nigg, Borrelli, Maddock, & Dishman, 2008) This theory includes three individual psychosocial variables; 1) goal setting that is related to behaviour through satisfaction, attainment and commitment to goals 2) motivation in the form of self-motivation and the barriers and relapses of 3) self-efficacy. The two contextual variables; life stress and physical activity environment may enable or impede the behaviour of maintaining exercise adherence directly or indirectly via the three individual psychosocial variables.

Physical Activity Maintenance Theory domain 1: Life stress

Unavoidable illness and injuries not related to either intervention, as well as family responsibilities, were identified as important sources of life stress that could affect exercise participation in our study in Chapter 5. The most common life stress mentioned was anxiety and/or depression, although these did not reach clinically important levels (an anxiety or depression score of 7 or higher as measured by the hospital anxiety depression scale) at 12 months for participants in either group (see Chapter 3). Our finding that participation in gym-based group exercise may result in better mental health outcomes may be important for exercise adherence beyond the first year of the program and warrants further follow-up.

Physical Activity Maintenance Theory domain 2: Goal setting

Encouragement from the exercise physiologists using goal setting was commonly mentioned by trial participants as a key facilitator of adherence for both intervention groups in Chapter 5. Chapter 3 did not include quantitative measures to analyse the achievement of each participant's baseline goals at 12 months

or a questionnaire such as a Goal Attainment Scale,(Turner-Stokes, 2009) and this could be an important measure to include in future research. To date, there is little evidence on the effective use of goal setting in the maintenance phase of an exercise program. (Bassett & Petrie, 1999; Evans & Hardy, 2002; Ziegelmann et al., 2006)

Physical Activity Maintenance Theory domain 3: Self-efficacy

The qualitative study (Chapter 5) revealed that participants who expressed higher self-efficacy regarding exercise identified as being more adherent to their program regardless of intervention group. Our findings were largely concordant with other work examining factors affecting participation in similar populations during the earlier adoption phase of exercise programs.(Freene et al., 2014) Our RCT (Chapter 3) did not include a measure of self-efficacy, however, it seems that this may also be important to include in future studies, given the importance self-efficacy has throughout adoption and maintenance phases of exercise programs. (Freene et al., 2014)

Physical Activity Maintenance Theory domain 4: Self-motivation

Chapter 5 identified common themes of self-efficacy and motivation in the form of either a belief in a positive health effect if they completed their prescribed program, or a fear of negative health consequences if they failed to maintain their participation. This supports previous research which has demonstrated that higher scores on measures of self-efficacy were significantly associated with participation in physical activity in older populations. (Perkins, Multhaup, Perkins, & Barton, 2008) It is likely that intrinsic determinants such as self-efficacy and self-motivation to exercise are equally important in chronic disease populations.

Physical Activity Maintenance Theory domain 5: Physical activity environment

External factors such as a welcoming physical activity environment and access to appropriate equipment clearly play an important role in the process of physical activity maintenance. Prior to the study, we anticipated that the gym-based program would produce superior adherence and mental health outcomes, most likely mediated via the social interaction that participants would have experienced at the gym. However, no change in our measure of social isolation was found to support this hypothesis. Chapter 5, however, identified that the centre based intervention may have improved social isolation by some participants forming their own informal 'peer support' networks around attendance at the gym.

Chapter 5 findings were largely concordant with other work examining factors affecting participation in similar populations during the earlier adoption phase of exercise programs.(Freene et al., 2014) This study found similar themes in their gym-based group, which primarily revolved around improved social interaction, whereas the convenience of a home-based program allowed easy integration into participants' daily routine as it eliminated transport and access barriers. This study also found no individual preference to improve exercise adherence in the adoption phase of either exercise intervention. (Freene et al., 2014)

Chapter 3's findings supported the systematic review (chapter 1) in that we identified no difference in adherence rates between the two follow-up approaches. The proportion of people fully adherent (defined as 3 sessions completed per week) was 34% in the gym group and 33% in the home group. Whilst we anticipated that gym attendees may have had superior adherence (and therefore clinical gains) given their access to exercise equipment that was familiar to them compared to improvised or unfamiliar equipment in the home-based group, this was not supported by the data. We also anticipated that factors such as immediate feedback or progression through the use of gym equipment and access to a greater range of equipment, would enable exercise to be completed at a higher intensity. However, neither translated to improved clinical gains or adherence rates in the gym intervention group.

The findings of considerable economic uncertainty in Chapter 4 along with similar clinical outcomes in Chapter 3 raises questions about the value of these two programs. The uncertainty of these findings of

chapter 3, 4 and 5 should be seen in its appropriate context. To date, clinical decision-makers could justifiably prescribe either gym-based or home-based intervention after the completion of a supervised short-term exercise program in a community based setting. If either intervention is already established in a community setting, then the other intervention is unlikely to be more efficient or cost-effective.

6.4 Thesis strength and limitations

6.4.1 Strengths

A key strength was the stakeholder engagement (researchers, therapists, exercisers, community health care and private gym users) to achieve the aims of this thesis in real life clinical settings. Engaging chronic disease participants in a long-term exercise trial is often challenging, and it is encouraging that the rates of people fully adherent (defined as three, 60 minute sessions completed per week) at 12 months was 34% in the gym group and 33% in the home group (chapter 3). These adherence rates exceed the WHO's global adherence rates 23% of adults aged 18 or older (men 20% and women 27%). Although past history of exercise was not analysed in chapter 3, this trial population typically had reported to researchers that they had never exercised before. Additionally, no participants reported any adverse events related to their exercise program participation across the 12 months.

A further strength was the long term follow up which allowed us to observe that the health outcomes attained at the end of the initial program were largely maintained at 12 months in both groups. Typically this population have multiple co-morbidities, poor or declining mobility, high risk of hospitalisation, physical de-conditioning, or a combination of these problems and their health status is expected to deteriorate. Unless effective follow-up interventions are in place, exercise participation usually declines following the completion of a short-term, supervised, pulmonary exercise program, with associated loss of the initial gains in clinical measures such as the 6-minute walk test distance (M. J. Berry et al., 2010; Ries et al., 2003)

6.4.2 Limitations

A limitation of chapter 3 and 4 was that the planned sample size of 114 participants was not met. We had lower statistical power than anticipated and it is possible that a Type II statistical error may have been made. A larger sample size may have narrowed down the confidence intervals in the randomised controlled trial and the size of the confidence ellipse in the cost effectiveness analysis. In addition, conducting a randomised controlled trial in a single-site outer-urban community health service may have resulted in findings with limited generalisability.

The majority of papers in the systematic review were of low quality and two studies were judged to be at high risk of attrition bias. (Brooks et al., 2002; Cockram et al., 2006) Seven out of eleven studies solely focused on people with chronic obstructive pulmonary disease therefore limited the generalisability of this review. Another limitation of the systematic review is the potential bias created from performing a meta-analysis and meta-regression on a small numbers of trials. This may not be an accurate representation of the underlying "true" effect of the full adherence intervention but reflect the "best available evidence" to date.

This field of study continues to be limited by varying definitions of adherence. The systematic review found the most common definition of adherence in the included studies was the proportion of participants completing or attending the prescribed amount of exercise sessions (n=10). Other adherence definitions included a "threshold" term, for example, "defined as performing at least 50% of prescribed exercise sessions". These variations of exercise adherence definitions make comparison between studies questionable.

The physical function tests chosen, despite having high validity and reliability data specific for this population do have limitations. More precise measures of cardiovascular fitness, skinfold measures (at the very least, for estimates of body composition), leg-press, bench press and either a submaximal or maximal aerobic capacity test may have provided far greater insight relating to potential adaptations in response to the intervention.

6.5 Future directions

Future research needs to compare the cost-efficiency and effectiveness with a “no follow up” control to inform clinical decision-makers which intervention is most worthwhile investing in. Future research could also take the form of a multi-centre trial across several different locations (regional vs metropolitan) to investigate whether geography influences the relative effectiveness and economic efficiency of either approach. Furthermore, a multi-centre trial would enhance the generalisability to a broader population of people with chronic disease.

There is a clear need for a standardised validated measure of exercise adherence that is responsive to change for future studies involving adults with chronic disease. Activity trackers such as Global Positioning System wrist watches or pedometers (for walking programs) may induce greater accuracy in self-reported adherence in future studies. Studies may also benefit from the inclusion of valid, reliable, and responsive measures of self-efficacy and individual goal attainment.

6.6 Thesis conclusion

There appears to be little difference in the effectiveness and cost-effectiveness of gym-based compared with home-based interventions for people with chronic diseases who had completed a short term supervised exercise program. A health clinician could justifiably employ either of these follow-up approaches in clinical practice. If a telephone based service is already in place, a gym-based service would be an unlikely option to replace it in a more effective manner. A gym-based approach is already in place, then a telephone-based option would equally be unlikely to replace it a more effective manner. Providing health coaching in parallel to exercise may improve self-efficacy and assist with removing many of the intrinsic and extrinsic barriers. Enablers for those in the gym-based group primarily revolved around improved social interaction whereas the home-based program was easily integrated into participants’ daily routine as it eliminated transport and access barriers.

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7.1 Appendix

Appendix A -Studies excluded from the review

No exercise group completed prior to randomisation (n=26)	(Brosseau et al., 2012), (Dean et al., 2012), (Hartigan, Rainville, Sobel, & Hipona, 2000), (Elsworth et al., 2011), (Jette et al., 1998), (Jolly et al., 2009), (Ma, King, Wilson, Xiao, & Stafford, 2009) , (Mead et al., 2007), (Morey et al., 1999), (Pearson, Burkhart, Pifalo, Palaggo-Toy, & Krohn, 2005), (Riley, Glasgow, & Eakin, 2001), (Taylor-Piliae & Coull, 2012), (Wang, Fetzer, Yang, & Wang, 2012), (Foy, Rejeski, Berry, Zaccaro, & Woodard, 2001) (Wilbur et al., 2008), (Woo et al., 2009), (Bentsen, Lindgärde, & Manthorpe, 1997),(Weir et al., 2000) (Maddison et al., 2015), (Aartolahti, Tolppanen, Lonnroos, Hartikainen, & Hakkinen, 2015), (Liu-Ambrose & Eng, 2015), (Hakestad, Torstveit, Nordsletten, Axelsson, & Risberg, 2015), (Chuter, de Jonge, Thompson, & Callister, 2015), (Aartolahti et al., 2015), (Berry et al., 2010), (Hiltunen et al., 2005),
Protocol paper (n=3)	(Dale et al., 2014), (Yardley et al., 2015), (Foster et al., 2014)
Participants did not have chronic conditions (n=5)	(Stineman et al., 2011), (Zoellner et al., 2011), (Horne, Skelton, Speed, & Todd, 2010), (Hsu, Wang, Chen, Chang, & Wang, 2010), (Brassington, Atienza, Perczek, DiLorenzo, & King, 2002)
No follow-up intervention to enhance adherence (n=3)	(Sniehotta, Gorski, & Araujo-Soares, 2010) (Martin & Woods, 2012), (Perk, Hedback, & Jutterdal, 1989)
Unable to extract adherence data (n=2)	(Hughes et al., 2010), (Elliott, Watson, Wilkinson, Musk, & Lake, 2004)
Follow up strategy not linked to adherence data (n=1)	(Mailloux, Finno, & Rainville, 2006)
No measure of adherence (n=2)	(Desai, Hughes, Peters, & Mermelstein, 2014), (Cooke, Moyle, Griffiths, & Shields, 2009)

Not a RCT, CCT or observational study (n=2)	(Desveaux, Rolfe, Beauchamp, Goldstein, & Brooks, 2014), (Wozniak, Soprovich, Mundt, Johnson, & Johnson, 2015)

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Appendix B– Full search strategy for Medline

Medline (Ovid Medline 1948 to Present with Daily Update)

Search	Terms	Terms	Limits	Hits
1	Participant	Osteoporosis OR Asthma OR Chronic obstructive airways disease OR Chronic obstructive Comorbidity OR pulmonary disease OR Pre-existing disease OR Co-morbidity OR Chronic disease OR Musculoskeletal OR Heart disease OR Stroke OR Cerebrovascular accident OR CVA OR Neurological OR Depression OR Type 2 diabetes OR Non-insulin dependent diabetes OR Arthritis OR Osteoarthritis		1581977
2	Participant[1]	Community Health OR Community Based OR Community Dwelling OR Adults		448266
3	Intervention	Phone OR Tele-health OR Telephone calls OR Follow up OR Advice OR Management strategies OR Reward OR Punishment OR Verbal Instructions OR Written Instructions OR Action Plan OR Goal Setting OR Coping Plan OR Positive Reinforcement OR Self-efficacy OR Barriers OR Education OR Reminder OR Counselling OR Information OR Motivational Interviewing OR Health Coaching OR Support OR Partnership OR Co-operation		9434924
4	Intervention[1]	Physical activity OR Physical intervention OR Exercise		275653
5	Outcome	Uptake OR Occasions of service OR Adherence OR Dose OR Compliance OR Patient Contact		1525829
6	Combined	(S1 AND S2) AND (S3 AND S4) AND S5	Humans English	685

Appendix C- Examples of qualitative questions to be asked:

How would you describe your experience during this project?

What do you think the benefits of participating in the gym-based/home-based exercise program were?

What were the negatives of participating in the gym-based/home-based exercise program?

How easy or difficult was it for you to participate in your prescribed program regularly?

What prevented you from participating in your prescribed program regularly?

What enabled you to participate in your prescribed program regularly?

What effect do you think your exercise program had on your social interactions and relationships?

How do you think a gym-based/home-based exercise program may have affected your social interactions and relationships differently?