School of Physiotherapy

Effectiveness of Self-Management Programs for People with Osteoarthritis of the Knee

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DECLARATION

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made. This thesis contains no material that has been accepted for the award of any other degree or diploma in any university.

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August 2011

Abstract

Chronic diseases are a major concern in terms of prevalence and disability in a progressively aging population. Osteoarthritis (OA) is a chronic condition that affects 15% of the population with up to 50% over the age of 65 years having radiological evidence of OA. Self-management (SM) is increasingly being utilized as a strategy to enable people to manage their chronic condition. There is conjecture as to the effectiveness of SM for arthritis with systematic reviews and meta-analyses citing only small, if any, benefits in terms of pain and functional improvements.

A disease specific SM education program for OA knee, known as the OAK Program, delivered by health professionals, was tested in a Quality Assurance study and found to show improvements in pain, function and quality of life. Recent evidence suggests there is increased mortality associated with OA of the knee, with a further increased risk for those with OA of the knee and restricted activity. With the improvements demonstrated in the Quality Assurance study, it was necessary to test this Program under a more rigorous study design.

In this doctoral research the OAK Program was compared to a control group in a randomised controlled trial (RCT) (Study 1). The aim of Study 1 was to determine whether people with osteoarthritis of the knee completing the OAK Program report improved quality of life, knee function and decreased pain compared with those managed conventionally.

One hundred and forty-six people with OA of the knee were randomised into either a control group or the OAK (Program) group. The OAK Program is a six-week intervention, with follow-up to six-months. The no-intervention/usual medical management control group had assessments at the same time-points as the OAK group: pre-intervention, post-intervention (8-weeks) and at six-months. The results of this RCT showed improvements in pain, physical function and quality of life in the OAK group when compared to a control

group, with improvements maintained to six-months. These positive findings added weight to the effectiveness of the OAK Program, and the next part of this doctoral research was to compare it with another self-management model.

The Arthritis Self-Management Program (ASMP) is the most accepted self-management model for arthritis but it has not demonstrated improvements in pain and function to any significant degree. It is generic in content and utilises lay leaders therefore the comparison with the OAK Program that is disease specific and uses health professionals would give information useful to determine the most effective self-management model for osteoarthritis.

In Study 2, the OAK Program was compared in a RCT to Stanford University's Arthritis Self-management Program (ASMP), a generic arthritis SM program facilitated by lay leaders (Study 2) with follow-up continuing to twelve-months. The aim of Study 2 was to test whether a greater proportion of people with osteoarthritis of the knee completing the OAK Program report clinically meaningful improvements in pain, knee function and quality of life, compared to those completing the ASMP.

One hundred and eighty people with OA of the knee were randomised into either the OAK group or the ASMP group. Participants and assessors were blind to group allocation. Study 2 methods were the same as Study1 with the exception of an extended follow-up period to 12-months.

Primary outcomes for both studies included pain, physical function and quality of life as determined by the proportion of minimal clinically important improvements and responder criteria achieved by participants in each group. Group by time differences using an ANOVA analysis were also computed for each variable.

Study 1 demonstrated significant in improvements in pain, physical function and quality of life compared to the usual medical management control group. The advantage of participating in the program was maintained for the six-

month follow-up period when, for ethical reasons the control group was offered the self-management program.

In Study 2 both groups received a self-management intervention and both groups demonstrated significant improvements in most primary outcome measures. The OAK Program participants however had greater improvements in pain and function compared to the ASMP group in the short term. The advantage of participating in the OAK Program was maintained through to the 12-month follow-up in VAS pain, and WOMAC and SF-36 Physical Function domains, but other outcomes became non-significant.

Physical function and pain decreased in the OAK group in both Study 1 and 2. This is unique to the OAK Program, as other arthritis SM programs have not demonstrated significant improvements in either pain or function. These findings are important, as pain and function are predictors of disability. The improvements in these measures suggest a functional improvement and in the context of the recent evidence of increased mortality associated with a decline in functional ability this is particularly relevant.

The inclusion of specific information on pain relief and exercise for people with OA of the knee in the OAK Program is likely to have an association with the improvements demonstrated in pain and function. This specific information is beyond the scope of lay leaders and it may be that a disease specific SM program for people with OA of the knee is more effective than a heterogeneous generic SM program for arthritis. However, since the mechanisms involved with successful SM are not clear, there may be other factors that play a role in the process since both the control group and ASMP group also achieved improvements.

The OAK Program demonstrated significant improvements in primary outcomes in both Study 1 and Study 2. The ASMP group also showed improvements in these outcome measures however none were significant compared to the OAK group.

The results of these studies demonstrate that the OAK Program is an effective SM program for people with OA knee, however Study 2 does not definitively determine which SM program is most effective therefore further research is required.

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LIST OF PUBLICATIONS

- Short and medium-term effects of an education self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals: a quality assurance study. *BMC Musculoskeletal Disorders* 2008, 9:117 S. Coleman, N.K. Briffa, G. Carroll, C. Inderjeeth, J. McQuade

- Effects of self-management, education and specific exercises, delivered by health professionals, in patients with osteoarthritis of the knee. *BMC Musculoskeletal Disorders* 2008, 9:133 S. Coleman, N.K. Briffa, G. Carroll, C. Inderjeeth, N. Cook, J. McQuade

- Self-management for osteoarthritis of the knee: Does mode of delivery influence outcome*? BMC Musculoskeletal Disorders* 2010, 11:56 S. Coleman, J. Rose, J. McQuade, G. Carroll, C. Inderjeeth, N.K. Briffa

Conference Presentations

- World Physical Therapy Congress 20-23 June 2011, Amsterdam, Holland. Oral presentation: *An Osteoarthritis Of The Knee Self-Management Education Program Delivered By Multidisciplinary Health Professionals; A Randomised Controlled Trial.* This presentation won an “Outstanding Abstract and Presentation Award”.

- World Physical Therapy Congress 20-23 June 2011, Amsterdam, Holland. Oral presentation: *Osteoarthritis Of The Knee; Self-Management Utilising Multidisciplinary Health Professionals Or Lay Leaders?*

- American College of Rheumatology Scientific meeting, November 2009. Philadelphia, USA. Oral presentation: *Self-management for*

osteoarthritis of the knee; health professionals or lay leaders? S. Coleman, J. McQuade, G. Carroll, C. Inderjeeth, N.K. Briffa

- Curtin University of Technology. August 2008. 6th International Meeting of Physical Therapy Science. Oral presentation: *Long and short-term effects of an education self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals*

- Change Champions: 2nd healthcare Without Walls: Delivering the best care in the best place. Brisbane, August 2007. Oral presentation: *Osteoarthritis of the knee- a targeted education and self-management program delivered by multidisciplinary health professionals shows clinically important improvements maintained to 12months*

- Innovations in Arthritis & Musculoskeletal Conditions Toolkit Seminar. Melbourne, 26th April 2007. Oral presentation: *Osteoarthritis of the knee- a targeted education and self-management program delivered by multidisciplinary health professionals shows clinically important improvements maintained to 12months.*

- APLAR - Asian Pacific League of Associations for Rheumatology Scientific meeting, Kuala Lumpur, Malaysia, August 2006. Oral presentation: *Self-Management Delivered By Health Professionals - The Effects Of Behaviour Modification, Education And Specific Exercises In Patients With Osteoarthritis Of The Knee.*

- Health Outcomes 2005: Making A Difference. Canberra, August 2005. Oral presentation**:** *Improving health outcomes for people with osteoarthritis of the knee combining health professional skills and self-management constructs*

- EULAR - European Congress of Rheumatology, Scientific programme, Vienna, June 2005. Oral presentation: *Effects of self-management,*

education, and specific exercises, delivered by health professionals, using behaviour modification in patients with osteoarthritis of the knee.

- Arthritis Foundation of WA, Health Professional Clinical Update in Musculoskeletal Diseases, April 2004. Oral presentation: *A Multidisciplinary Approach to Self-Management*

- Chronic Condition Self-Management Conference, Melbourne, November 2003. Oral presentation: *In chronic disease management symbiotic relationships of health professional's skills and self-management techniques can produce long term positive health outcomes.*

Posters

- American College of Rheumatology Scientific meeting, November 2006. Washington DC, USA. Poster presentation: *Clinically Important Improvements in Pain, Stiffness, Function and Quality of Life in Patients with Osteoarthritis of the Knee 12 Months Following a 6 Week Education and Self-Management program Delivered by health Professionals*

- EULAR – European Congress of Rheumatology, Allied Health Professionals, poster presentation, Vienna, 8-11 June 2005: *Effects of self-management and education, delivered by health professionals, using behaviour modification and specific exercises in patients with osteoarthritis of the knee.*

ABBREVIATIONS

OA	Osteoarthritis
OAK	Osteoarthritis of the knee program
ASMP	Arthritis Self-Management Program
SM	Self-management
SE	Self-efficacy
HP	Health professional
CBT	Cognitive behavioural therapy
RCT	Randomised controlled trial
QA	Quality assurance
VAS	Visual analog score
WOMAC	Western Ontario and McMaster University Osteoarthritis Index
SF-36	Short Form 36 questionnaire
TUG	Timed up and go
GH	Global health
GI	Global improvement
CI	Confidence interval
MCII	Minimal clinically important improvement
LVCF	Last value carried forward
MRI	Magnetic resonance imaging
SCT	Social cognitive theory

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CHAPTER 1

Introduction.

Among an ageing population, the prevalence of chronic disease will increase resulting in a major impact on health care costs (Woolf 2001). Osteoarthritis (OA) of the knee is a prevalent chronic condition and one of the most common causes of musculoskeletal disability (Abramson and Attur 2009). Complementary to conventional medical care, self-management (SM) is a primary care intervention that is considered to be beneficial in the management of people with chronic illness (Abramson and Attur 2009). The term SM is described as

"…any formalized patient education programme aimed at providing the patient with the information and skills necessary to manage their condition within the parameters of the medical regime." - The Expert Patient Approach, p22.
(Department of Health 2001)

and

"…are based on developing the confidence and motivation control over life with a chronic condition"- The Expert Patient Approach, p6.
(Department of Health 2001)

Unlike traditional patient education programs, SM programs aim to achieve more than providing information to increase knowledge. They also aim to change health behaviour and health status, (Lorig 2002) and are designed to assist people to manage their condition (between physicians visits), by teaching them how to cope with their symptoms, including the physical and psychological consequences of living with a chronic disease.

In recent years SM has become an accepted intervention in the management of chronic illness. Developed countries have increasingly incorporated SM into their health budgets as a means of addressing the prevalence of chronic illness in a progressively aging community (Bury, Newbould et al. 2005). The application of SM for people with arthritis originated in the 1980's (Lorig and Gonzalez 1992), and has become increasingly popular, particularly since the advent of the Bone and Joint Decade.

The recognition of arthritis as a major health burden by the World Health Organization (Woolf and Pfleger 2003) resulted in the period from 2000 to 2010 being acclaimed as the Bone and Joint Decade (BJD). The aims of the BJD (Tsou and Chng 2002) were:

1. To raise awareness of the growing burden of musculoskeletal disorders on society.
2. To empower people to participate in their own care.
3. To promote cost-effective prevention and treatment.
4. To advance understanding of musculoskeletal disorders through research and so improve prevention and treatment.

Despite its prevalence and the associated disability burden, in Australia arthritis only became a national health priority in 2002. Arthritis is now acknowledged as being third only to cardiovascular and psychological conditions in its prevalence in this country (Knox, Harrison et al. 2008).

SM is considered to be an effective strategy in the treatment of arthritis (Chodosh, Morton et al. 2005). Although generally thought to be cost-effective there is little evidence to support this suggestion. Some contrary evidence suggests that this is actually not the case with respect to either health or social care costs (Patel, Buszewicz et al. 2009). Despite the lack of evidence, Australia and the UK have incorporated SM into national health care initiatives (Jordan and Osborne 2007) and in the USA, one large health care organization has incorporated SM into their funding program (Nolte, Elsworth et al. 2007).

Across the chronic disease spectrum various models of SM, either disease specific or generic, have been employed. These models include individual, group-based, postal and internet programs (Warsi, Wang et al. 2004). Face-to-face interaction with health professionals is one important component of some programs, especially where medication compliance is necessary. In other versions, trained lay leaders deliver more generic programs, often based on information that is pre-scripted to guarantee uniformity.

The application of SM has been shown to be more effective for people with hypertension, diabetes and asthma than those programs designed for people with arthritis (Chodosh, Morton et al. 2005; Griffiths, Foster et al. 2007; Jordan and Osborne 2007; Nolte, Elsworth et al. 2007). In fact, there is little robust evidence to support the value of the application of SM in arthritis. Furthermore, there is lack of consensus regarding the most effective type of SM program and the most successful means of program delivery for this condition.

In a meta-analysis of chronic disease SM programs, Chodosh, Morton et al (2005) identified the difficulties in isolating the factors that result in greater efficacy of SM programs. This appears to be due to discrepancies among the different disease states and differing components included in SM programs (Chodosh, Morton et al. 2005).

Chodosh, Morton et al (2005) then suggested (based on the literature and with the addition of expert opinion), that there were five possible components of successful SM strategies. Thus patients who receive interventions *tailored* to their specific needs and circumstances are likely to derive more benefit than those receiving interventions that are generic. Equally, in a *group setting* patients are more likely to benefit being with others affected by the same condition than from an intervention provided in some other setting.
Feedback is also important since patients are more likely to derive benefit from a cycle of intervention followed by some form of individual review with the provider of the intervention than from interventions where no such review exists. In addition a *psychological emphasis* would be valuable since patients are more likely to derive benefit from a psychological intervention than from interventions where there is no psychological component. Further, patients who receive interventions directly from their medical providers (physicians or primary care providers) and identified as *medical care*, are more likely to derive benefit than those who receive interventions from nonmedical providers (Chodosh, Morton et al. 2005).

For arthritis, as for other forms of chronic diseases, it is difficult to determine the most effective model of SM. This difficulty arises because of the discordance between programs, study designs and outcome measures used in SM trials and reported in the literature. Outcome Measures in Rheumatoid Arthritis Clinical Trials - OA Research Society International (OMERACT-OARSI) has proposed a simplified set of responder criteria to address this issue (Pham, van der Heijde et al. 2004). These criteria were the combined opinions of academic researchers and representatives of both health agency and pharmaceutical companies. The proposed criteria covered three domains: pain, function and patient's global assessment. For each of these domains a response is defined by both an absolute change and a relative change (per cent) in the variable. Six scenarios were evaluated (A, B, C, D, E, F) – three considered pain as the first response variable and three considered pain and/or function (Pham, van der Heijde et al. 2004). The treatment effect was similar in all six scenarios however scenario D, (which has been used to report the responder analysis in both trials reported in this thesis) had higher sensitivity and specificity than the other scenarios for hip OA and was chosen by the expert panel to represent the OMERACT-OARSI set of responder criteria (Pham, van der Heijde et al. 2004).

The criteria used for Scenario D is: An improvement of ≥50% and an absolute change of ≥20 points on a 100 point scale in pain or function, OR an improvement of at least two of the following: An improvement of ≥20% and an absolute change of ≥10 in two of pain, function and global health.

Despite the introduction of these criteria, there is still a paucity of robust trials with which to make evidence based decisions on the most effective SM program for people with arthritis.

Most commonly, the Stanford University Arthritis SM Program (ASMP) has been the industry standard for arthritis, however there is no unequivocal evidence to support the widespread use of the ASMP. Systematic reviews (Warsi, LaValley et al. 2003; Newman, Steed et al. 2004; Warsi, Wang et al. 2004; Newbould, Taylor et al. 2006) of SM interventions for various chronic

diseases have reported a trend towards a small benefit from arthritis programs, with the majority being the ASMP or derivatives of the ASMP. The results of these reviews however, have been found to be largely insignificant and some suggestion of publication bias has been described (Warsi, Wang et al. 2004; Chodosh, Morton et al. 2005). Most trials reported short-term changes only, with few trials following participants beyond six months.

Several limitations of the ASMP have been identified. These include the generic content of the program that is necessary because it is facilitated by lay leaders; the fact that participants with any type of musculoskeletal condition are included in the same group and the fact that the drop-out rate associated with the ASMP appears to be high. (Warsi, Wang et al. 2004; Chodosh, Morton et al. 2005). In contrast, successful SM programs for such disorders as asthma, diabetes and hypertension generally use health professionals for program facilitation. Such programs have the added advantage that they also include specific information on clinical disease management, assist the participants to correct erroneous health beliefs and offer structured exercise within the SM program (Griffiths, Foster et al. 2007).

One study (Cohen, van Houten Sauter et al. 1986) has made a comparison between programs facilitated by lay leaders and health professional leaders. The study compared 34 people in a lay-led group with 34 people in a group led by health professionals, with 32 controls. Assessments were done at baseline and again at 4 months. Improvements in exercise knowledge and practice were demonstrated in both groups, compared with their baseline values with authors concluding that there was little difference between the groups led by lay leaders or health professionals. However the study design required all leaders both lay and health professionals, to deliver the same scripted program. Thus the knowledge and skills of the health professionals may not have been optimally utilised, providing the potential for a flawed outcome (Cohen, van Houten Sauter et al. 1986).

The major benefit of lay leaders is that they have the capacity to be role models as they often have musculoskeletal conditions themselves (Lorig and

Holman 2003). Health professionals with their knowledge and skills can also have a powerful influence as models for the groups' members (Taylor and Bury 2007). Modelling has the potential to transmit knowledge and skills to which people may aspire, particularly if the information is perceived to be important and relevant (Bandura 1977).

As well as the discussion created by the difference in group leadership, there is also speculation about the mechanisms that contribute to successful SM. There is little concrete evidence to support any particular aspect of these programs with the exception of medication compliance (Chodosh, Morton et al. 2005). Chronic illnesses that encompass pain, such as arthritis, are more complex than those that are predominantly medication focused, for example hypertension. Though all chronic disease management requires behaviour modification and coping strategies if they are to be effective, arthritis SM interventions also need to include medication compliance (Newman, Steed et al. 2004).

The literature suggests that SM may not be effective across all chronic diseases (Jordan and Osborne 2007; Nolte, Elsworth et al. 2007) and that further investigation could help clarify whether SM programs for arthritis are beneficial and worthwhile (Warsi, LaValley et al. 2003; Newman, Steed et al. 2004; Chodosh, Morton et al. 2005; Nolte, Elsworth et al. 2007). Weingarten, Henning et al (2002) in their meta-analysis of chronic disease management programs comment on the diversity of programs and suggest that to determine the effectiveness and costs, evaluations need to compare different types of interventions (Weingarten, Henning et al. 2002). It has been suggested that disease specific programs delivered by health professionals are an essential component of successful SM (Jordan and Osborne 2007; Taylor and Bury 2007). One program developed by Arthritis Western Australia represents a disease specific SM program for people with OA of the knee. It is known as the OAK Program and specifically employs health professionals for program facilitation. This program was tested in a quality assurance (QA) study that demonstrated improvements for patients in pain, function and quality of life (Coleman, Briffa et al. 2008a). A description of this

study is included in the Appendix. The results of the QA study were encouraging and it was decided to test the OAK Program further in two stages using a rigorous study design, a randomised controlled trial (RCT).

Aims of the thesis

The specific aims developed for the studies that constituted this thesis were:

1. To determine whether a disease specific SM program designed for delivery by health professionals (namely the OAK Program) would improve pain, function, and quality of life in individuals with OA of the knee.
2. To test the OAK Program further by comparing it with the industry standard for arthritis SM, the ASMP.

To fulfil these aims, two RCTs were designed. In the first (Study 1) changes in response to the OAK Program were compared with responses in a comparable control group that had no SM intervention. In the second study, responses to the OAK Program were compared with responses to the ASMP in a group of people with arthritis of the knee.

Study 1:

Hypothesis

To determine whether a disease specific SM program for people with osteoarthritis of the knee (the OAK program), implemented by health professionals, would achieve and maintain clinically meaningful improvements in health related outcomes compared with a control group.

This study was registered with the Australia and New Zealand Clinical Trial Registry, number: 12607000080426. Curtin University of Technology, Human Research Ethics Committee approved this study (HR141).

Study 2:

Hypothesis

A greater proportion of people with OA of the knee that complete the OAK Program will achieve a minimal clinically important difference in pain, function

and quality of life, at eight weeks, six and twelve months compared to those who complete the ASMP.
This study was registered with the Australia and New Zealand Clinical Trial Registry, number: 1260700001460. Curtin University of Technology, Human Research Ethics Committee approved this study (HR12).

Ethical considerations

Both Studies 1 and 2 were conducted at Arthritis WA, a community setting that is close to public transport and has available infrastructure for study management and co-ordination. Copies of consent forms, participant study information, doctors study information, SF-36 and WOMAC licenses, case report forms, assessment forms, Curtin University ethics approval, for both studies are included in the Appendix. Arthritis WA has a licence from Stanford University to conduct the ASMP and it is also licensed to train lay leaders for facilitation of the ASMP.

Study information was stored according to National Health and Research Council guidelines (Australian Government 2009) in hard copy in a locked filing cabinet, and electronically on one password protected computer that was available only to the study co-ordinator. Patient demographics were stored separately from all data and case report forms (CRFs) contained no identifying information. CRFs were identified by participants' initials and study number only. The codes for these were stored on the password-protected computer. At completion of the study, this information will be archived in a secure location for 7 years and will then be destroyed.

Prior to commencing enrolment for Studies 1 and 2, ethical approval was obtained from the Human Research Ethics Committee, Curtin University of Technology. Arthritis WA also gave approval for the studies, and the OA Knee Advisory Committee that had guided the QA study was invited to continue in that capacity with the OAK Program in the next two phases of the study.

Advisory Committee

In keeping with usual policy at Arthritis WA, an Advisory Committee was established to contribute to progress development and subsequent evaluation of the OAK Program. The Advisory Committee consisted of two rheumatologists, a geriatrician/rheumatologist, and an associate professor in physiotherapy. The members of the Advisory Committee met on average every 2-3 months initially and twice yearly thereafter unless there were complicating issues. Updates, abstracts, and correspondence were sent to members of the Advisory Committee via email between meetings.

The Advisory Committee contributed to the selection of outcome measures used to measure changes in pain, quality of life, muscle strength, physical function and range of motion in the knee. They also advised on a range of areas involved in the study design, for example identifying an acceptable method of diagnoses for OA of the knee; inclusion and exclusion criteria; randomisation procedure; assessment time-points and procedures.

The next chapter will review the literature relevant to the issues associated with OA of the knee and the use of SM as a management technique for people with this disability.

CHAPTER 2

Literature Review

Chronic disease can be seen as evolving along a continuum. A disease-free state undergoes an asymptomatic biological change, progresses to clinical illness and, depending on severity, can continue on to impairment and disability. The continuum can include the development of complications and disability in some cases (National Public Health Partnership 2001). Most health care initiatives are directed initially towards prevention, however, once the condition has developed then the approach of choice becomes curative at the various points along the continuum.

Osteoarthritis

This review is about one such chronic condition, OA, and approaches to management that involve the individual understanding and taking responsibility for their own disease. Initially, the disease process and prevalence, the risk factors associated with it, and the associated aetiology and diagnosis will be examined, with particular emphasis on OA of the knee, since it is the focus of this thesis. Following this, the ideas that have led to the development of SM approaches of interest to the present work will be presented. Finally, a particular SM program for OA of the knee will be examined in the studies that form the basis of this thesis.

It is recognised that some causal agents affect more than one chronic condition (Guh, Zhang et al. 2009). Guh, Zhang et al (2009), in their meta-analysis of co-morbidities relating to obesity, use obesity as an example of this since it can be attributed, in part, to a number of different co-morbidities. Such co-morbidities include cancer (kidney, colorectal, prostate, ovarian, uterine/endometrial, esophageal, pancreatic, and postmenopausal breast), type II diabetes, cardiovascular disease risk (hypertension, coronary artery disease, congestive heart failure, pulmonary embolism, stroke), gallbladder disease, chronic back pain, OA, asthma, and diabetes (Guh, Zhang et al. 2009). Public health initiatives that target one health problem, such as

obesity, may in fact be affecting multiple chronic illnesses. It is estimated by the Australian Bureau of Statistics for those over the age of 65 years, that the majority will have three or more chronic conditions (Caughey, Vitry et al. 2008; Australian Bureau of Statistics 2009). When people have two or more chronic conditions, their quality of life is likely to be significantly reduced, which may result in more frequent visits to general practitioners and an increase in health expenditure (National Public Health Partnership 2001).

In 2007, Access Economics prepared a report for Arthritis Australia on the impact of musculoskeletal conditions (Access Economics 2007). The report indicates that musculoskeletal conditions are the second most costly national health priority, behind cardiovascular disease, and more Australians are diagnosed with arthritis than any other national health priority condition. This same report highlights a number of facts about arthritis including that it is more prevalent in women (19.9%) than men (17%) and that 62% of all people with arthritis are of working age (15-64 years). Arthritis connected productivity costs and absenteeism account for $7.6 billion per year (Access Economics 2007) thus in terms of disability burden, arthritis is second only to depression. The report indicates that the total financial costs for arthritis in 2007 were estimated to be $23.9 billion a sum that equates to approximately $1,100 per Australian.

Further information presented in this same report (Access Economics 2007) described OA as the most common form of arthritis accounting for 46% of those with a diagnosis of arthritis affecting 10% of the population. Dieppe and Lohmander (2005) suggest it is also more common in women than men over 65 years of age and the prevalence of OA of the knee is similarly greater in women than men. Forty per cent of the population will have OA by the age of 65 (Access Economics 2007), and it is the third leading cause of life years lost to disability (DALYS) (March and Bagga 2004).

Caughey, Vitry et al (2008) conducted a systematic review of chronic diseases focusing on six Australian national health priority conditions (arthritis, asthma, cancer, cardiovascular disease, diabetes mellitus and

mental health problems). Twenty-five studies were included in the review with the aim of reporting the prevalence of co-morbidities. The findings suggest that one in two people presenting to their GP with a chronic illness will also have arthritis (Caughey, Vitry et al. 2008). In addition, people with OA suffer from co-morbidities that have an adverse effect on physical function more frequently than the general population (Kadam and Croft 2007). The combination of OA plus another chronic illness has more serious effects on health status than the sum of the two conditions alone (Kadam and Croft 2007). Moreover those people with a chronic illness such as OA who have additional co-morbidities are more likely to be prescribed medication for each condition that may result in polypharmacy with the associated risk of unwanted medication interactions and adverse effects (Caughey, Vitry et al. 2008; Dawes 2010).

There is no single identified cause of OA, however several risk factors have been identified. These include age, heredity factors, sports injuries, occupational risk factors, obesity, and biomechanical factors (Australian Institute of Health and Welfare 2005).

Age is the most significant risk factor having the highest correlation with OA (Abramson and Attur 2009). Age seems to increase the risk of developing OA, and more women than men are affected after the age of 50 years. It occurs more often in the hip in men, but more commonly in the hand, knee and feet in women (Jordan, Kington et al. 2000). With advancing age, factors including weight gain, decreased proprioception, muscle weakness and gait abnormalities contribute to increasing stress on joints.

There appears to be a genetic predisposition for OA (Jordan, Kington et al. 2000; Leveille 2004), however the precise link with the genetic contribution to the pathogenesis of OA is difficult to determine and it is probable that multiple genetic factors influence disease severity (Felson 2009). One study of 130 identical and 120 non-identical female twins, aged between 48-70 years, demonstrated a clear genetic link in women with OA involving the

hand and/or knee, however the genes involved have yet to be identified (Spector, Cicuttini et al. 1996).

In a review of the development of the scientific understanding of arthritis Abramson and Attur (2009) report that some genes involved with disease risk in OA have been located, however the genetic components may differ between specific joints and also between sex and race. They also point out that since OA is so prevalent in the population it is difficult to analyse the precise genetic contribution to the incidence and severity of OA (Abramson and Attur 2009). Valdes, Doherty et al (2007) compared the genes of 603 people with OA with 596 age-matched controls without OA and concluded that there is a complex interaction between genetic variants that can predict the risk of OA (Valdes, Doherty et al. 2007). In addition to the genetic component, mechanical and metabolic risk factors can initiate and perpetuate the biomechanical changes that result in OA (Abramson and Attur 2009). For example, body mass index, knee pain, medial tibial bone area are all influenced by genetics (Jones, Ding et al. 2003). It may be that in those with a genetic predisposition to OA, the disease is triggered by an injury resulting in OA of that injured joint (Jordan, Kington et al. 2000). Some elite athletes such as soccer or football players are predisposed to developing OA (Lane 1996), but for those who undertake recreational physical activity there is little evidence to show that they are at any greater risk of developing OA (Conaghan 2002; Sharma, Kapoor et al. 2006).

Sports injury involving menisci or tendon rupture in youth will increase the relative risk of developing OA. In Sweden in 1989, 219 young soccer players with anterior cruciate injuries were followed for 14 years (mean age at 14 year follow-up was 38 years). At this follow-up 154 remained in the study and 122 consented to having an X-Ray, of these 78% had radiograph evidence of OA (von Porat, Roos et al. 2004). Lohmander et al (2004) followed 106 female soccer players, with anterior cruciate injury due to soccer, mean age at assessment was 31 years. At the 12 year follow-up 103 females consented to X-Rays and of these 42% had radiographic OA (Lohmander, Ostenberg et al. 2004). In a review of joint injury in young adults, Roos

(2005) states that in practical terms 50% of people who suffer injury to the menisci or tendons in their 20's will experience knee pain and functional limitations resulting in lifestyle restrictions around 14 years after the initial injury.

Occupational risk seems to have a relationship with OA. Although cartilage requires a certain amount of loading to stay healthy (Sharma, Kapoor et al. 2006), excessive bending and loading may contribute to the risk of developing OA (Conaghan 2002) and biomechanical abnormalities may cause uneven loading and exacerbate the pain associated with OA (Conaghan 2002; Sharma, Kapoor et al. 2006). Occupational risk factors are fairly well known in men, but most studies do not include women at home who are subject to domestic and childminding activities (Sharma, Kapoor et al. 2006) so the impact of occupation on women may be underestimated.

Ethnicity may be a contributing factor, but there are conflicting theories regarding ethnic risk factors. African American males are more likely to develop OA of the hip than their Caucasian counterparts, and their X-Rays show more severe involvement. The OA is often bilateral and is associated with greater disability than that found in Caucasian males (Jordan, Kington et al. 2000).

Obesity has a direct association with OA (Creamer, Lethbridge-Cejku et al. 1997; Sowers 2001; Nevitt 2002), pain, and disability (Okoro, Hootman et al. 2004). Those with OA who are overweight are likely to show increased disease progression on X-Ray and the risk is increased fourfold in women, especially for the knee (Pascual 2003) and to a lesser extent for the hip (Jordan, Kington et al. 2000). The risk for OA knee is increased by 15% for every additional increment of BMI above 27 (Sowers 2001) with 50% of middle-aged women with OA in one knee progressing to bilateral OA of the knee within two years (Nevitt 2002). Obesity is the number one preventable cause of OA knee in women and second in men after trauma (Nevitt 2002). It is generally accepted that weight loss will result in an improvement in pain

and disease progression for those with a diagnosis of OA (Focht, Rejeski et al. 2005).

The forces acting on the knee are 3-6 times body weight during normal activities of daily living (Huang, Chen et al. 2000) therefore the heavier the weight the greater the load the knees endure. Obesity associated with biomechanical abnormalities such as joint malalignments are thought to have a combined effect on the progression of OA. Obesity alone exacerbates OA, but the effect is more pronounced in the presence of valgus or varus deformity of the knees (Sharma, Lou et al. 2000). The distribution of load is more critical where there is a varus deformity and the effect of increasing BMI will be more pronounced on the varus knee (Sharma, Kapoor et al. 2006). This suggests that the loading effect of a BMI of 30 will be greater on a varus knee than on a normally aligned knee. Thus walking for those with OA and noticeable varus will tend to create the conditions for a fourfold increase in medial OA progression (Felson 2005; Sharma, Kapoor et al. 2006).

With advancing age, BMI gradually increases up to about the sixtieth year when it then starts to gradually decline (Elia 2001). About the same time there is an increase of adipose tissue in the omentum, visceral fat increases, fat is redistributed into muscle (Zamboni, Mazzali et al. 2005), and there is loss of lean muscle mass and changes in metabolism, all of which lead to changes in body shape and weight. Such changes occur at a time of gradual decrease in physical activity (Elia 2001). This decline in energy turnover (energy intake versus output - in the form of physical activity) is likely to be accentuated in those with chronic diseases (Elia 2001).

There is a strong association with disability in those with OA as BMI increases (Okoro, Hootman et al. 2004). This is worrying as there is a world trend in western countries for an increasing prevalence of obesity, which will potentially result in an increase in the prevalence of disability.

Postural alignment of the hip, knee and ankle influence load distribution and that in turn has an effect on the structure of the OA knee and the resulting functional outcome (Sharma 2003; Abramson and Attur 2009). As indicated previously, it is thought that varus and or valgus malalignment may be both a cause of OA knee and a result of it (Sharma 2003). Varus and valgus malalignment increase the medial and lateral load in the knee and are strong predictors of structural and functional deterioration (Sharma, Song et al. 2001; Fransen and McConnell 2008). Malalignment also strongly predicts joint space narrowing on X-Ray, loss of cartilage on MRI (Felson 2009) and bone marrow lesions that are also predictive of disease progression (Abramson and Attur 2009).

Aetiology of Osteoarthritis

For many years it was thought that OA was a consequence of "wear and tear" and thus part of the aging process. The view was that the "wear and tear" had a destructive impact on cartilage. Currently, OA is considered to be the result of a number of different conditions that cause both biological and mechanical destabilization of the joint (Abramson and Attur 2009). It involves all the tissues of the joint and may be initiated by a variety of factors including genetic, developmental, metabolic and traumatic (Abramson and Attur 2009). Osteoarthritis resulting from this combination of factors is characterized by morphologic, biochemical, molecular and biomechanical changes that result in tenderness, joint pain, loss of range of movement, crepitus, effusion, and inflammation (Creamer, Lethbridge-Cejku et al. 1997; Sharma, Kapoor et al. 2006).

It is suggested that the primary cause of OA may be the disruption of the subchondral bone (Felson and Neogi 2004) with increased stiffness that transmits more load to the overerlying cartilage (Bobinac, Spanjol et al. 2003). It is understood that the cartilage relies on the condition of the underlying subchondral bone for its integrity (Creamer, Lethbridge-Cejku et al. 1997; Hunter and Conaghan 2006). Articular cartilage has two main functions – it absorbs impact by deforming under load, and it provides a

smooth surface for joint movement. If subchondral bone becomes too stiff, it is no longer effective as a shock absorber and this in turn affects the cartilage (Creamer, Lethbridge-Cejku et al. 1997).

Cartilage defects and the volume of subchondral bone are thought to be associated with OA (Ding, Cicuttini et al. 2005) especially in those who are obese. In people with OA, increased bone turnover in the arthritic joint, decreased bone mineral content and stiffness, and a decrease in trabecular bone have been observed in subchondral bone structure when compared with normal bone, suggesting that bone metabolism may play a role in the progression of OA (Wluka, Forbes et al. 2006).

Oestrogen has an effect on the tissues associated with OA of the knee (bone cells, chondrocytes and synoviocytes) interacting with collagen synthesis, bone stiffness and inflammation (Sowers, McConnell et al. 2006). Decreasing oestrogen levels at menopause also appear to influence the occurrence of OA. The incidence of the disease dramatically increases around menopause (Sniekers, Weinans et al. 2008), suggesting that oestrogen possibly has some protective effect. At 50 years of age, the ratio of the incidence OA in females to males is 10:1 with the onset of symptoms occurring perimenopausally or within 5 years of menopause (Roman-Blas, CastaÒeda et al. 2009).

A further consequence of menopause is sarcopenia, or age related muscle loss which is characterised by progressive loss of skeletal muscle fibres and lean muscle mass (Leveille 2004) and its replacement by fat and connective tissue (Hamerman 1997). Sarcopenia is thought to be a combination of hormonal and immunological changes that occur with advancing age (Poehlman, Toth et al. 1995). Cytokines that cause inflammation may also play a role in the loss of muscle and its relationship with disability (Leveille 2004). It is associated with Vitamin D and oestrogen in women and testosterone and physical activity in men (Leveille 2004). It appears the loss occurs in fast twitch, or type 2 muscle fibres and aerobic type exercise is not

effective in reducing this loss. Resistance, or strength training is required to maintain or increase muscle mass and strength (Hamerman 1997).

There is a gradual decline in quadriceps strength associated with OA (Suetta, Aagaard et al. 2007). Whether quadriceps weakness precedes the development of OA or is a consequence of OA is not clear (Lewek, Rudolph et al. 2004). Sensorimotor dysfunction is associated with the loss of function and the evolving disability associated with quadriceps weakness, impaired proprioception and impaired neuromuscular protective reflexes (Hurley 2003). It is suggested that in some cases quadriceps weakness precedes pain and evidence of joint damage on X-Ray (O'Reilly, Jones et al. 1998). Furthermore, the combination of muscle sensorimotor dysfunction, impaired articular sensory input and impaired neuromuscular protective reflexes and shock absorption capacity may be responsible for excessive, rapid, jarring to joint loading during gait (Hurley 2003).

Studies of the association between ROM and limitation in physical activities are scarce (Steultjens 2000). There is a natural decline in ROM with advancing age, however the extent of the decline is not well documented (Roach and Miles 1991). As with muscle weakness, ROM is also affected by OA. Periarticular connective tissue becomes fibrotic, contracted or shortened when the joint is inactive or immobilized due to the pain of OA, resulting in a decline in ROM (Huang, Yang et al. 2005). In addition the muscles around the knee may become shortened further adding to loss of range. After a relatively short period of time – as little as 3 weeks, the muscles start to become contracted causing instability of the joint (Huang, Yang et al. 2005). The combination of instability, musculoskeletal impairments such as lower limb weakness and a decline in ROM are related to function and disability, thus lower extremity ROM, and lower limb muscle force are often predictors of functional ability (Beissner, Collins et al. 2000; Steultjens 2000).

Inflammation may play a role in OA, and C-reactive protein has been found to be raised in some people with OA (Conaghan 2002), however, sensitive assays are required for accurate measurement of this phenomenon. The

extent to which inflammation contributes to OA remains controversial and there is still much that is not understood in relation to the overall cause of OA.

Pain and Osteoarthritis

Pain, a topic that comprises a moderate proportion of the OAK program (central to the studies that make up this thesis) is one of the most common topics of discussion amongst those participants of the OAK studies; hence it is discussed here at some length. Pain is a symptom of OA that is often reported and is usually the reason that people seek medical attention (Conaghan 2002; Felson 2005). X-Ray imaging shows poor correlation between pain and structural damage (Dieppe and Lohmander 2005), however recent studies using MRI have shown that the site of pain correlates with bone oedema and synovial hypertrophy (Conaghan 2002; Felson 2005). Other associations with pain include knee effusions, synovial thickening, and lesions such as tendonitis and bursitis.

One study using a non-anaesthetised subject undergoing arthroscopy of both knees revealed interesting facts about pain within the knee joint. Although the data were obtained from only one subject, both knees were subjected to arthroscopy and the sensations were the same in both knees (Dye, Vaupel et al. 1998). The most sensitive areas were identified as the ligament insertion sites, synovium and patella fat pad. When probed, the patella was not found to be sensitive, however the insertion of fluid into the patella caused great pain which suggests that the pain associated with OA may be caused by an increase in bone pressure (Felson 2005).

Although the process of pain sensation is not fully understood, it is thought that pain in OA is the result of both local and central factors (Dieppe and Lohmander 2005). There are two types of neurones responsible for the sensation of pain. One neurone produces only nociception (pain) and the other responds to both mild and acute pressure (Felson 2005). In addition, it is thought that there is also disruption to the central nervous system

perception of pain sensitivity (Kosek and Ordeberg 2000). Inflammation influences the input from these neurons causing increased stimulation. The increased stimulation has the effect of causing hypersensitivity, that is a stimulus that was not previously painful becomes so, and the receptor field enlarges so that there is a greater area to be stimulated (Kosek and Ordeberg 2000; Felson 2005) resulting in a lower threshold for pain.

Cartilage does not contain pain fibres, but they are present in surrounding structures such as ligaments, synovium, joint capsule, bone and bone marrow and part of the meniscus (Dieppe and Lohmander 2005). Bone marrow lesions are thought to be a strong predictor of OA progression (Felson 2005; Hunter and Conaghan 2006) and bone marrow oedema is associated with joints most likely to be painful. This association is not clearly understood, however, using MRI there is evidence of osteonecrosis, excessive fibrosis and extensive bony remodelling which may provide an explanation for the prevalence of malalignment and bone marrow lesions (Felson 2005).

As the disease progresses pain will occur frequently at night (Kosinski, Janagap et al. 2007), and will become more chronic as the condition deteriorates. Stiffness is a common symptom and may limit the initiation of movement in the affected joint (Dieppe and Lohmander 2005). Eventually the movement within the joint will become restricted until ROM is decreased significantly, which may cause disability and impact on activities of daily living such as walking or climbing stairs (Fransen and McConnell 2008).

There is a lack of information associating pain with the decline of function. Two studies are of interest – the MAK study (Sharma, Song et al. 2001) which recruited 237 people with primary knee OA and investigated the role of malalignment and its effect on pain and function; and the OASIS study (Vignon, Valat et al. 2006) – a systematic literature review that aimed to determine recommendations for certain activities for people with OA knee or hip. Both studies found an association between pain and function, but the results were not statistically significant when adjusted for SE interaction

(Sharma, Kapoor et al. 2006). In a systematic review describing the course of deterioration, pain and function in OA, van Dijk, Deeker et al (2006) looked at 18 studies with long–term follow up of 3 years. The van Dijk, Deeker et al (2006) team reported that most studies of the progression of OA focus on radiological changes (where signs of radiological deterioration are common, but the association between function and these changes is contradictory) rather than on functional deterioration. This is despite the fact that there is limited evidence for the association between worsening pain and function over time due to the lack of high quality studies (van Dijk, Deeker et al. 2006).

Van Dijk, Veenhof et al (2010) further examined the prognosis of limitations in activities in OA of the knee or hip in a 3-year cohort study that aimed to describe the course of limitations in activities of those people with OA knee and hip with respect to function, co-morbidity and cognitive function (van Dijk, Veenhof et al. 2010). Their findings suggested that on an individual (but not group) level, prognostic factors for worsening function included an increase in pain, reduced muscle strength, reduced ROM, and an increased number of co-morbidities (van Dijk, Veenhof et al. 2010).

Diagnosis of Osteoarthritis

A clinical diagnosis of OA may be made based on the history of symptoms and the association of pain that occurs with activities involving the effected joint (Jordan, Kington et al. 2000). X-Rays are often used to establish a diagnosis and monitor disease progression, however it is known that clinical changes do not always correlate with changes on X-Ray (Dieppe, Cushnaghan et al. 1997) and changes on X-Ray do not always reflect those related to pain.

The Kellgren and Lawrence (1957) grading system suggests that X-Rays should be read by the same observer or preferably by two observers in consultation. This system is most commonly used to gauge OA using the presence of osteophytes and the degree of joint space narrowing as markers

of disease severity (Hunter and Conaghan 2006; Sharma, Kapoor et al. 2006). Joint space narrowing is due to loss of cartilage, and the presence of osteophytes and joint space narrowing are typical findings on X-Ray, however, some patients with established OA do not show progressive changes on X-Ray over time. In addition, the relationship among osteophytes, joint space narrowing, pain and function is not proven, though it is stronger with osteophytes than joint space narrowing. Knee pain has an association with joint space narrowing which advances more rapidly in the presence of pain (Hunter and Conaghan 2006).

Since the progression of OA is variable from person to person, X-Ray may not be the most satisfactory method of gauging disease progression. Magnetic resonance imaging (MRI) is more sensitive than X-Ray as it allows the visualisation of soft tissue, subchondral bone and cartilage, including any defects that may be present. It is used increasingly in the diagnosis of OA (Ding, Cicuttini et al. 2005; Felson 2005; Hunter and Conaghan 2006). MRI is useful as the surrounding structures within the joint are important factors in understanding the pathogenesis and disease progression and can viewed easily using this imaging method.

Pain is often a useful marker, and with reliable measures such as the Western Ontario McMaster OA index (WOMAC) (Bellamy 2005), pain, stiffness and function can be assessed to monitor disease progression (Jinks, Jordan et al. 2002).

The Knee

Of special interest to the current studies is OA of the knee. That being the case, it is essential to examine the anatomy of this joint in some detail. Moore and Dalley (2006) describe the knee as the largest and one of the most complex joints in the body (Moore and Dalley 2006). It is a synovial joint that is required to perform a number of complex manoeuvres, and compared with the hip joint is relatively unstable because it is not well protected by surrounding muscles. It has a hinge-like movement that allows flexion and

extension with a degree of internal and external rotation when in flexion (Moore and Dalley 2006).

The knee is the junction of two bones (the femur and tibia), the ends of which are not in contact with each other but are covered with hyaline cartilage and contained within a joint capsule. Surrounding the capsule are ligaments and muscles that perform a stabilising function (Moore and Dalley 2006). Synovial fluid lies within the joint capsule and allows the two ends of the bones to move without friction. It is a complex fluid that can be thought of as tissue in which the matrix consists of a transudate of plasma supplemented by hyaluronans (Arden and Cooper 2005).

The knee joint gets its stability from the structures surrounding it, including the capsule, ligaments and active muscle control (Williams, Chmielewski et al. 2001; Moore and Dalley 2006). These structures prevent separation of the two bones ends. To give stability, the cartilage that forms the menisci has a natural tendency to expand, acting as a spacer within the joint and bringing the capsule and ligaments under tension. The meniscii also distribute stress across the joint and provide shock absorption (Brindle, Nyland et al. 2001). The two opposing forces of the cartilage trying to push the bones apart, and the capsule, ligaments and muscle preventing it, maintain the stability of the structure. If the cartilage loses its volume or thickness or the ligaments become slack or the muscles weaken, the joint will become unstable which may lead to a risk of developing OA (Woo, Debski et al. 1999). Conversely, these events can also be a consequence of OA (Arden and Cooper 2005). The knees form an important element of the main weight bearing structure of the body and carry the load of many daily activities such as walking, standing, getting up and down from sitting, and climbing stairs therefore injury or OA can significantly effect activities of daily living (Moore and Dalley 2006).

The knee is commonly involved in OA with a prevalence of 34% in people aged 65 years or older (March and Bagga 2004; Access Economics 2007; Kadam and Croft 2007). As outlined earlier, it involves the entire joint and

includes loss of cartilage that is associated with changes to underlying bone (growth of osteophytes and sclerosing or thickening of the bone), changes in the soft tissue within the joint - including the synovium, ligaments and muscles (Jordan, Kington et al. 2000).

The presence of OA in the knee compromises the ability to get up from a chair, climb stairs and walk (McCarthy, Mills et al. 2004) and has more negative effects on these activities than any other condition (Jordan, Kington et al. 2000). OA is more debilitating when it occurs in the weight bearing joints as it has a greater impact on mobility (Moore and Dalley 2006). People suffering from OA of the knee are likely to be less active resulting in further reduced joint mobility, strength, fitness, balance, and general health (Brady 2003; Sharma, Kapoor et al. 2006).

Nuesch, Dieppe et al (2011) examined the mortality of OA knee and hip in a population based cohort study of 1163 people with a 14-year follow-up. The authors highlighted the fact that very little is known about the mortality associated with OA, and found that people with OA knee are at a higher risk of death when compared with the general population. These authors claim that the most striking finding is that people with walking disability are at an even higher risk of death than those people with OA who are more active. The authors suggest the possibility of two pathways accounting for this association. The first is that the cardiovascular co-morbidity along with the association of pain results in less physical activity and a greater use of non-steroidal anti-inflammatory drugs. The second pathway is an association with chronic inflammation that may be causally involved with cardiovascular related disease. The authors suggest that the aim of OA interventions should be to encourage people with OA to participate in a level of activity that meets with the World Heath Organization guidelines. Furthermore, the authors suggest than an aggressive approach to encouraging physical activity even with painful OA seems justified (Nuesch, Dieppe et al. 2011).

Management of OA

Increased physical activity and weight loss are an important part of the management of OA. Combined, they will not only benefit the condition but will improve muscle bulk, strength, balance, endurance and will reduce the number of falls in the older members of the population (Elia 2001). Additionally, physical activity and weight loss may also prevent the threshold of disability being reached which will help to maintain functionality (Elia 2001). In this section, the various approaches to the management of OA will be considered.

Exercise appears in many guidelines for the treatment of OA (Brosseau, Robinson et al. 2003; Hurley 2003; Focht, Rejeski et al. 2005; Sharma, Kapoor et al. 2006). Although there is consensus on the benefits of exercise, many published recommendations are not supported by evidence (Roddy, Zhang et al. 2005). Areas in need of supportive evidence include the contraindications for exercise, predictors of response to exercise, ways of increasing adherence and promoting physical activity, the role of exercise and muscle strength in slowing the progression of the disease and the best method of delivering exercise as an intervention in subjects with hip or knee OA (Brosseau, Robinson et al. 2003; Roddy, Zhang et al. 2005).

According to a Cochrane Collaboration published review of exercise regimens for OA of the knee, evidence of reduced pain and improved function as an outcome are reported (Fransen and McConnell 2008). However, neither the type nor intensity of exercise can be recommended based on this review because of the large variation in exercise content in the thirty-two programs included (Fransen, McConnell et al. 2001).

Regular exercise not only strengthens muscles and improves flexibility, it also promotes cardiovascular fitness, reduces fatigue, improves vitality and social functioning, and has been shown to be effective in decreasing anxiety and depression (Westby 2001). Regular exercise does not appear to have a detrimental effect on disease progression (Westby 2001; Hurley 2003). The

combination of diet and exercise is more effective than dieting alone and also results in improvements in pain and physical function (Creamer, Lethbridge-Cejku et al. 1997; Evans and Cyr-Campbell 1997; Focht, Rejeski et al. 2005).

The recommendation of the American College of Sports Medicine is that resistance exercise is an important component of any overall exercise program and that strength training is the only effective way to limit the effects of sarcopenia (Roubenoff and Castaneda 2001) in the elderly (Evans and Cyr-Campbell 1997; Hurley and Roth 2000). Age related decline in muscle is not inevitable, and skeletal muscle will adapt to the demands placed on it. The more sedentary the lifestyle, the weaker the muscle will become (Doherty 2003). Thus it appears that physical activity is a critical factor in maintaining the structure and function of skeletal muscle (Kirkendall and Garrett 1998). A Cochrane Collaboration review of 121 resistance training trials for older people which included 6700 participants, concluded that resistance training had small but significant results that translated into improved physical function resulting in improvements in the performance of simple activities such as walking, climbing steps, or standing up from a chair (Liu and Latham 2009).

Indeed, strength training is also important in relation to endurance capacity. As people age and become inactive, it may be that they are no longer able to exercise in an aerobic capacity to the extent required to balance energy input with output such that they can maintain a healthy weight and promote muscle strength (Kirkendall and Garrett 1998).

Resistance type exercise not only increases muscle mass, but also has an effect on energy balance in elderly people (Kirkendall and Garrett 1998). People who participate in resistance training require 15% more energy to maintain their body weight as a result of an increase in metabolic rate (Evans and Cyr-Campbell 1997). Resistance type exercise is essential when elderly people are trying to lose weight as it is the only form of exercise that will preserve lean muscle mass (Doherty 2003). Since weight reduction is

frequently included in guidelines in the treatment of OA (American College of Rheumatology 2000), this fact should be carefully considered.

For older persons, performing resistance exercise two or three times per week has been shown to reduce physical disability and improve function in areas such as balance, gait, rising from a chair and climbing stairs (Liu and Latham 2009). Resistance exercises have a large positive effect on muscle strength, on aerobic capacity and on the reduction of pain in older people with OA (Latham, Anderson et al. 2003).

Aerobic exercise has been recommended for the management of many chronic diseases, arthritis being no exception. Both high and low impact aerobic exercise are suggested as the intensity of exercise for the treatment of OA does not appear to be significant (Brosseau, Robinson et al. 2003). Walking results in the largest improvements in pain and physical activity, depression improves with aerobic dancing, and disease activity improves most with aquatic exercise (Bartels, Lund et al. 2007) while aerobic capacity appears to improve with most forms of exercise but is greatest with cycling (Westby 2001). Thus it is suggested that an exercise regimen that includes a variety of different aerobic activities would be optimal (Brosseau, Robinson et al. 2003).

In a review of soft-tissue aging and musculoskeletal function, Buckwalter, Woo et al (1993) describe age related changes to tendons and ligaments that, like muscles, also undergo deterioration contributing to frailty and disability (Buckwalter, Woo et al. 1993). These structures become stiff resulting in a decrease in ROM and a subsequent decrease in functional ability (Buckwalter, Woo et al. 1993). As tendons and ligaments become fibrous with age, there is a decline in the mechanical properties of strength, stiffness and their ability to withstand stresses (Nordin, Lorenz et al. 2001). Flexibility exercises improve the mobility of contractile and non contractile tissues such as ligaments and tendons (Cafiero and Maritz 2003).

Feland and Myrer (2001) studied the effects of 3 different stretching routines on 62 elderly subjects (mean age 84 years). They commented that most studies have been focused on younger subjects with little literature available on the effects of stretching on older subjects (Feland, Myrer et al. 2001). Their findings suggested that stretching maintained for 60 seconds and repeated four times per day for six weeks can result in a greater rate of improvement in ROM in older people (Feland, Myrer et al. 2001). Although stretches maintained for shorter durations also improved flexibility, the benefits of holding the stretch for longer periods have been shown to be greater (Feland, Myrer et al. 2001; Cafiero and Maritz 2003). Furthermore, for the benefits of improved ROM to be maintained, stretching must be continued over time.

Exercise in water is often recommended as a treatment for people with OA. While short term benefits have been identified, no long term effects have been proven (Bartels, Lund et al. 2007). The water is thought to relieve pain, relax muscles and provide an environment where the effect of gravity on joints is reduced. The resistance provided by water requires effort, so ROM and to some degree, strengthening exercises may be performed in water.

Comparisons of land based exercise and exercise in water, have demonstrated that both result in improvements in quadriceps strength, walking speed and distance (Foley, Halbert et al. 2003; Silva, Valim et al. 2008). Hydrotherapy is useful as a form of aerobic exercise for people with OA as the buoyancy of the water reduces joint loading, allowing increased intensity of exercise. Hydrotherapy also has the added benefits of heating the affected joint with pool temperatures being around 33 degrees Celsius. It is thought that the soothing effect of the warm water relaxes muscles and encourages a greater range of joint movement (Becker 2009).

Since OA is a condition that varies significantly in severity, exercise needs to be individually prescribed according to age, extent of joint involvement and co-morbidities (Roddy, Zhang et al. 2005). Exercise “dosage” is a factor of frequency, intensity and duration and is also dependent on the individual’s

level of exertion. In addition, since exercise needs to be adhered to over the long term for benefits to be maintained, it usually requires some kind of supervision or monitoring (Fransen, McConnell et al. 2001).

Long-term adherence to exercise programs is difficult to achieve (Roddy, Zhang et al. 2005). Perhaps this is because many of the exercise programs do not mimic common lifestyle settings since they are often conducted in tertiary health settings using sophisticated equipment and expert supervision (Thomas, Muir et al. 2002). The attrition rate in such situations is linked to the intensity of the exercise program, that is the higher the intensity the greater the drop out rate, particularly in the long-term (Cox, Burke et al. 2003). It may be that to encourage participants' long term adherence, exercise programs may need to be initially designed to be simple, easy to implement and practical and of a lower intensity (Brosseau, Robinson et al. 2003; Marks and Allegrante 2005). Explanations of the rationale for exercise, demonstrations, and strategies to improve SE are necessary to encourage people to participate in habitual exercise, with regular follow-up being necessary to motivate people to continue long term (Hurley 2003; Marks and Allegrante 2005).

It is difficult to compare exercise regimens since there is a large degree of variability between outcome measures, assessment techniques, frequency, intensity and duration reported (Westby 2001). When determining significant improvements in study populations, for those people who have mild to moderate disease, the lack of severity of their OA makes it difficult to demonstrate improvements. Commonly used outcome measures that use self-reported pain and physical function questionnaires may exhibit a "ceiling response", and potential benefits in terms of increasing endurance capacity will not be reflected in the results (Fransen, McConnell et al. 2001).

Balance

Falls occur in 30% of the population over the age of 65 years, and of these 20% will require hospitalisation (Gillespie, Gillespie et al. 2003). Many of

those people who fall will not regain their former function and will become disabled (Gillespie, Gillespie et al. 2003; Hill and Schwarz 2004). In Australia, the incidence of falling is considered to be serious enough to warrant it being classified under the injury prevention national priority area (Hill and Schwarz 2004). Given that balance is often compromised in people with OA, the risk of falling represents a significant problem (Hinman, Bennell et al. 2002). Quadriceps weakness, impaired proprioception along with the other deficits associated with aging increase the risk of falls in those with OA (Hinman, Bennell et al. 2002).

Balance requires that the centre of gravity remain within the limits of stability within the base of support (Yim-Chiplis and Talbot 2000). Most activities of daily living will require a combination of dynamic, static and reactionary balance (Berg 1989). For example, standing on one leg will require good static balance (maintaining the centre of gravity within the base of support during standing or sitting) (Wooley, Czaja et al. 1997) and dynamic balance (maintaining the centre of gravity within the base of support while moving) (Wooley, Czaja et al. 1997). Reactive balance is a response to an external disturbance and anticipatory balance is a reaction to an expected disturbance (a bus slowing down to stop) (Yim-Chiplis and Talbot 2000).

The central nervous system is continuously involved in balance. The cerebellum coordinates limb motion, postural sway, upright posture during walking, generates the rhythmic motion and coordination involved in flexor and extensor muscle activation, and is involved in reactionary and anticipatory balance control (Morton and Bastian 2004). Sensory and motor neurons are continually adapting and adjusting to sensory input. It is widely reported that strength training and exercise, including specific balance exercises are beneficial for balance and falls prevention strategies (Gardner, Robertson et al. 2000; Carter, Khan et al. 2001; Gardner, Buchner et al. 2001; Robertson, Devlin et al. 2001; Day, Fildes et al. 2002; Gillespie, Gillespie et al. 2003; Liu-Ambrose 2004).

Thermotherapy

Non-pharmacological treatment of OA often includes thermotherapy, usually in the form of heat or ice packs applied to the affected area. In a review of the physiological basis of cryotherapy and thermotherapy, Nadler et al (2004) describes heat as relieving pain by relaxing muscles and improving circulation to the area (Nadler, Weingand et al. 2004). Cold is thought to reduce pain by promoting vasoconstriction thus blocking nerve endings (Nadler, Weingand et al. 2004). Both methods of pain relief are easily utilised in a home situation.

There is little solid evidence demonstrating that either heat or cold are effective treatments for OA because of the difficulty associated with conducting blinded trials, the small sample sizes and differing study designs of the published studies (Brosseau, Yonge et al. 2003). Despite this the use of thermotherapy and ice in particular is included in the OMERACT-OARSI recommendations for the management of OA hip and knee (Zhang, Moskowitz et al. 2008).

Ice appears to be more effective in relieving the symptoms of OA as well as achieving a reduction in swelling, and a significant improvement in range of motion and function (Brosseau, Yonge et al. 2003).The effect on pain is less clear, although the combination of ice and massage has been shown to have a significant effect on pain (Zhang, Moskowitz et al. 2008). Cold application needs to be carefully monitored in order to avoid a rebound vasodilation (Brosseau, Yonge et al. 2003). No significant improvements when using heat packs have been reported.

Summary

OA is the most common form of arthritis. OA affecting the knee and is considered to be a combination of different factors that result in both biological and mechanical destabilization of the joint (Abramson and Attur 2009). It involves the entire joint and surrounding muscles ligaments and cartilage within the joint capsule. It is thought that subchondral bone

disruption causes increased stiffness that results in cartilage defects over time (Felson and Neogi 2004) and is characterized by morphologic, biochemical, molecular and biomechanical changes that produce symptoms of tenderness, joint pain, loss of range of movement, crepitus, effusion, and inflammation (Creamer, Lethbridge-Cejku et al. 1997; Sharma, Kapoor et al. 2006).

The most common joint affected is the knee (Access Economics 2007). OA of the knees can be debilitating as the knees are load bearing joints that are involved in many daily activities such as walking, standing, getting up and down from sitting, and climbing stairs. Therefore OA of the knee can significantly affect activities of daily living (Moore and Dalley 2006). This is an important consideration because of the recent evidence demonstrating that the mortality associated with OA knee is higher than that of the general population and those people with OA knee who have walking disability are at an even greater risk of early death than their more active counterparts with OA (Nuesch, Dieppe et al. 2011).

Risk factors include: age, heredity factors, sports injuries, occupational risk factors, obesity, and biomechanical factors (Australian Institute of Health and Welfare 2005).

Diagnosis is by clinical symptoms, X-Ray, or MRI. X-rays provide information mainly on bones with poor definition of cartilage and surrounding tissue whereas MRI is capable of visualizing all structures within the joint.

Pain is a central feature of OA and is usually the reason that people seek medical attention (Conaghan 2002; Felson 2005). Occurring frequently at night (Kosinski, Janagap et al. 2007), it will become more chronic as the condition deteriorates. Stiffness is also a common symptom limiting the initiation of movement in the affected joint (Dieppe and Lohmander 2005) and in some instances range of movement is decreased significantly, which may cause disability and limit activities of daily living such as walking or climbing stairs (Fransen and McConnell 2008).

Exercise and weight loss appear in many of the treatment guidelines for OA (Brosseau, Robinson et al. 2003; Hurley 2003; Focht, Rejeski et al. 2005; Sharma, Kapoor et al. 2006), with recommendations that aerobic, resistance, flexibility and balance exercises be incorporated into an exercise regimen (Hurley and Walsh 2009; Liu and Latham 2009). Resistance exercise is also beneficial for age related muscle loss and the associated decline in balance (Hinman, Bennell et al. 2002). Water based exercise is considered to be an appropriate form of exercise for OA since the buoyancy of the water reduces joint loading, allowing increased intensity of exercise and the soothing effect of the warm water relaxes muscles and encourages a greater range of joint movement (Becker 2009). It is difficult to prescribe a precise exercise regimen as there is a large degree of variability between outcome measures, assessment techniques, frequency, intensity and duration, making comparisons difficult in studies of exercise and OA (Westby 2001).

In the next section one approach to the management of OA, namely SM, which has become increasingly important as a result of the work of Lorig and Gonzalez (1992) will be examined. The concept of SM is a major component of this thesis.

Self-Management

SM consists of a number of different components and is considered to be beneficial in the management of OA. Since it is an integral part of the OAK program, both the theoretical framework and the individual elements that constitute SM will be presented in some detail. Although the components of SM vary depending on the chronic disease to which it is applied, those discussed here are considered particularly relevant to OA.

Barlow (2002 p178) describes SM as the

> "…individuals ability to manage the symptoms, treatment, physical and psychosocial consequences and life-style changes inherent in living with a chronic condition"
>
> (Barlow, Wright et al. 2002), p178.

In the 1980's Kate Lorig and colleagues at Stanford University developed the first SM program with a knowledge-based focus that was thought to result in behaviour change (Lorig and Gonzalez 1992). However, once it became apparent that education alone did not result in behavioural changes (Newman, Mulligan et al. 2001) Albert Bandura's Social Cognitive Theory (Bandura 2001) was incorporated into the constructs of the Stanford SM model. The model was structured to enhance behavioural changes by the use of goal setting, group interaction, modelling, and social persuasion (Lorig and Holman 2003). The program became known as the Arthritis Self Management Program (ASMP).

As SM programs have evolved, the emphases within the programs have developed differences depending on the chronic illness to which they are directed. The inclusion of an education component is important where the chronic illness involves the use of medications (Newman, Steed et al. 2004; Warsi, Wang et al. 2004; Chodosh, Morton et al. 2005). Self-management interventions for OA that aim to teach patients how to manage their symptoms and how to moderate day-to-day activities to suit their needs with respect to their state of health, usually incorporate a considerable education content (Pajares 1996). With arthritis SM, pain management is a priority, along with physical and psychological functioning (Newman, Steed et al. 2004). The combination of SM and education compliments medical care and is thought to enhance the overall management of OA (Von Korff 1997). Health education, which is just one component of SM has a prolonged benefit (up to 4 years) in reducing the pain of OA, and this result has been replicated in a number of independent samples (Lorig, Sobel et al. 2001). Research suggests that improvements of 20% in OA symptoms over and above that attributable to medical management alone, can be achieved using patient education interventions (Pajares 1996; Ettinger, Burns et al. 1997). Despite the positive reports, SM programs have limitations.

These limitations are generally agreed to be attributable to several factors mainly related to the lack of a strong research base for the use of SM. Much of the published data is based on post hoc mail outs to determine

improvement (Lorig, Mazonson et al. 1993). Most do not have randomised controlled study designs or have methodological problems (Lorig, Sobel et al. 1999; Barlow, Turner et al. 2000). Additionally, volunteers recruited for SM programs may themselves be motivated to succeed, and therefore may not represent the general population (Taylor and Bury 2007). Most importantly, the precise mechanism related to any success of SM is not entirely understood (Newman, Mulligan et al. 2001; Bodenheimer, Lorig et al. 2002).

In addition, there have been few papers published on the long-term effects of SM (to 12 months). Barlow, Turner et al (1998) reported that people having completed the ASMP in the UK experienced improvements at 12 months, however, this was not a randomised controlled trial (Barlow, Turner et al. 1998). In fact, only three RCTs have followed patients' long term progress and each of these had mixed groups of rheumatoid arthritis and OA while only two involved the use of the ASMP (Bodenheimer, Lorig et al. 2002; Newman, Steed et al. 2004). Thus it is difficult to suggest that SM for people with arthritis has established benefits, even though SM programs, particularly the ASMP are widely supported.

The OAK program, central to this present work, utilizes Bandura's social learning theory (Bandura 2001) which has a central concept of self-efficacy and cognitive behavioural therapy (CBT) based on clinical psychology approaches (Newman, Mulligan et al. 2001; Newman, Steed et al. 2004) including self-talk, relaxation, guided imagery, and visualisation in its theoretical framework.

In order for behaviour to change, several elements need to be present. Initially, there must be a strong desire to perform or modify a behaviour and few barriers to understanding and performing the behaviour. The individual must have the skills required to undertake the behaviour, a belief that the behaviour has value and that the change is desirable from an individual and societal perspective (Elder, Ayala et al. 1999). Thus, there must be an element of readiness in considering the use of SM for particular chronic disorders.

Stages of Readiness for Self-Management

Some people respond better than others to SM. There are those who will undertake behavioural changes inherent to SM, and those who will not. It has been suggested that for SM to be effective, those who attend programs must be at a stage where they are receptive to the concepts of SM.

Von Korff (1997) and Keefe, et al (2000) describe 5 different stages of readiness.

- Pre-contemplation: In this stage, people are often unaware that they have a problem and are unlikely to modify their behaviour.
- Contemplation: In this stage, people are aware of their problem and are contemplating taking action to improve their condition however, they are not yet committed to take action.
- Preparation: This is a decision making stage. People are ready to take action in the immediate future.
- Action: Efforts are made to make change. These people may already have made changes to their behaviour.
- Maintenance: Changes have been made and these people are working to maintain and stabilise their behaviour changes (Von Korff 1997; Keefe, Lefebvre et al. 2000).

The ability to identify people at these stages would be useful for improving cost effectiveness by modifying existing SM programs to cater for peoples' needs during these stages. To recruit people at the Preparation, Action and Maintenance stages and to include strategies to identify those people who are at a stage where they would most benefit from SM may be a more effective use of resources. Additionally, these stages may also be a useful predictor of early drop out and responder success (Keefe, Lefebvre et al. 2000).

Bandura (2005) has a slightly different perspective on stages of readiness. He describes three stages. The first stage includes people who are highly

motivated. They have high levels of SE and also have positive expectations for behaviour change. Bandura (2005) suggests that these people will succeed in accomplishing their goals with only minimal guidance (Bandura 2005).

People in Bandura's (2005) second stage have far more self-doubts. They will make half hearted attempts at behavioural change, are quick to give up, and are unsure about the benefits of the activities they are attempting. They need more guidance and support in order to succeed. Individuals in the third stage have little chance of success if left on their own. Far more guidance and encouragement are required, as they believe that their health is beyond their control, and that attempts at SM and behaviour change are futile. They will need constant guidance and encouragement. However, they may succeed if small goals are achieved – leading to improved feelings of SE (Bandura 2005).

Recently, SM has become more comprehensive, and information as well as both practical and psychological issues have been added to the content of SM programs (Newman, Mulligan et al. 2001). The concept of SE, based on Albert Bandura's social cognitive theory (Bandura 2003), is central to many SM programs.

Social Cognitive Theory

Bandura's theory, formulated in 1986, differed from the current theorists' views of the day in that it suggested that internal influences, or the individual's perception of their own ability, was the most important determinant of success, whereas other theories placed the emphasis on external or environmental forces. (Pajares 2002; Stone 2003). Bandura is one of the chief proponents of SE. He believes that it is the prime motivator underlying successful SM because people need to believe that the actions they undertake will produce the desired outcomes - otherwise there is little incentive to act or persevere (Bandura 2005).

The components of arthritis SM programs, that is, goal setting, problem solving, pain management techniques, and modelling, are thought to result in improved SE (Newman, Steed et al. 2004). This is significant because not only does SE predict health outcomes, it also allows people to manage their condition without altering the disease itself. It achieves this by allowing the person to have a heightened sense of confidence and a feeling of greater control (Bandura 2005).

Education alone is not enough to result in behavioural changes (Newman, Mulligan et al. 2001) and SE beliefs are themselves critical factors in how well knowledge and skill are acquired initially (Pajares 2002). While SE is a powerful determinant of success, people still require skills and knowledge to achieve their goals, that is the information needs to be considered important and valuable before it is acted upon (Gist and Mitchell 1992).

Confident people expect that they will have positive outcomes. SE will influence the choices that people make and also how much effort they put into an activity (Bandura 2004). The higher their sense of SE, the longer they will persevere when faced with obstacles and the more resilient they will be when faced with adversity. Quick and easy success will not promote resilience. Those who overcome obstacles through perseverance will become stronger and will be more likely to stick to activities and rebound after setbacks. Problem solving is thought to help provide people with the skills necessary to overcome setbacks without giving up (Bandura 2001).

SE will affect cognition and emotional reactions. Those with high levels of SE will face a problem as a challenge to be mastered rather than viewing it as an insurmountable hurdle. With success, will come enhanced levels of SE (Pajares 2002). Having internal or self-motivation is likely to result in greater success in achieving desired outcomes than being externally motivated (told to do something by another). It also results in more motivation to initiate relevant activities (Tillema, Cervone et al. 2001; Williams, McGregor et al. 2004). Self-initiation of behaviours likely to improve health outcomes results

in a greater feeling of control, enhanced SE and better long-term adherence to changes in health behaviour (Williams, McGregor et al. 2004).

SE is identified as one of the factors that predict improved physical function over time especially in combination with weight loss, exercise and pain control. It is suggested that these factors need to be address when treating OA (Sharma, Cahue et al. 2003).

A key element of Bandura's social cognitive theory is that individuals have self-beliefs that allow them to exercise control over their thoughts and actions (Bandura 2001). It is these self-beliefs that are the essence of SE. Bandura's theory states that certain cognitive capabilities are influential in the process of determining control.

Pajares (2002) in an overview of social cognitive theory describes self-beliefs in the following terms: the capacity to symbolise, forethought, vicarious learning and self-regulation (Pajares 2002). Symbolising allows the extraction of meaning from cognitive things. It allows the storage of information that will help in decision making later on, and it allows learning from the modelled behaviour of others. Forethought allows for planning a course of action, anticipation, and solving problems. Forethought permits the anticipation of consequences without actually engaging in the behaviour. Vicarious learning (related to Bandura's (1998) vicarious learning and to modelling) is so effective because through vicarious learning, information can be gained that will be useful for future action. Experience is acquired without actually undergoing the behaviour and learning can occur without making mistakes. If the modelled behaviour is valued, it will be adopted and repeated in the future. Self-regulatory mechanisms include self-evaluation of behaviour and actions that allow modification or changing the course of action. It also includes self-reflection which allows people to make sense of their experiences and to alter behaviour and thinking as necessary (Pajares 2002).

These processes are involved with cognition, motivation, affect and selection.

SE beliefs determine how people think, motivate themselves, feel and behave (Bandura 1994). Many people have the knowledge, education and motivation to undertake SM, but do not succeed in performing the necessary behavioural changes in their daily life due to a lack of SE (Schreurs, Colland et al. 2003).

Pajares (2002) in his overview of social cognitive theory also describes the formation of SE beliefs from four primary sources that include: mastery experience, vicarious experience, social persuasion and mood. Pajares (2002) suggests further that mastery experience is the assessment of action taken based on previous performance. These results assist in the development of beliefs about capabilities relating to the outcome of the performance. Bandura (1998) states that the most effective way of strengthening the sense of SE is through mastery experiences (Bandura 1998). Usually a good outcome will result in higher SE and a poor outcome will result in lower SE (Pajares 2002). In other words, SE will improve as success is achieved in tasks that have been attempted.

Vicarious experience also promotes robust SE. Observing similar people succeed raises the onlooker's perception of their own abilities (Bandura 1998). The onlooker however, needs to perceive that the person modelling the behaviour has similar attributes to themselves, and that the activity will benefit them. Modelling sends messages through which people can learn skills and behaviour (Bandura 1999) and in SM programs, leaders are able to model behaviour themselves in the anticipation that participants will undertake these behaviours.

SE beliefs are developed as a result of social persuasion. Social persuasion is also used in SM, and persuaders (group facilitators) play an important role in the development of individuals' self-beliefs (Pajares 2002). Group influences can enhance participant's beliefs in themselves, which will enable participants to boost their efforts and be more likely to succeed in activities (Bandura 1998).

Mood also influences SE (Pajares 2002). Depression leads to poor performance, whereas a positive mood enhances the feeling of SE (Bandura 1998). Similarly, affect will also influence success and may play a role in setting SE perceptions and the standards of tasks attempted. Depression may lead to setting higher standards that slightly exceed the scope of SE expectations that ultimately become self-defeating (Bandura 1999). Even with familiar tasks, people who are depressed may set higher standards for performance than normal, which may inevitably lead to failure to complete the task (Tillema, Cervone et al. 2001).

With a poor sense of SE, new activities will promote a heightened sense of anxiety, which may result in dwelling on inadequacies, and perceived environmental dangers (Pajares 2002). Thus worry about possible threats is likely to have an adverse effect on functioning (Bandura 1994). With a stronger sense of SE, bold and threatening activities are more likely to be viewed as a challenge rather than a threat. This sense of efficacy will also determine what goals are undertaken and the extent of motivation to achieve them (Bandura 2001).

Because pain is often a significant feature of OA, pain management becomes an essential element of SM programs. The next section will consider this element.

Although SE is accepted as an important component of many SM programs, including arthritis there are critics of its assumed importance. Taylor and Bury (2007) suggest that there is no clear evidence to indicate that SE is responsible for changes in health status, and that the role SE plays may be overstated (Taylor and Bury 2007). These same authors question whether SE is an independent variable relating to SM capability, and also question whether SE is a cause or a result of coping well with a chronic illness. Both Taylor and Bury (2007) and Newbould, et al (2006) cite Lorig's 1999 chronic diseases SM trial that studied 952 people over 6 months (Lorig, Sobel et al. 1999). Both papers point out that although there were improvements in SE, there was not a corresponding improvement in "physiological well-being"

(Newbould, Taylor et al. 2006; Taylor and Bury 2007). Rogers et al (2008) in their review of The United Kingdom's Expert Patients Programme (EPP) that uses Lorig's Chronic Disease SM Program nationwide, also questions the role of SE as an outcome rather than a process and the importance of it in relation to SM (Rogers, Kennedy et al. 2008). Indeed, Williams (2010) suggests that despite the commonly perceived notion that SE is responsible for changes in expected outcomes, the reverse may in fact true, that is, the expected outcomes that a person perceives will influence their degree of SE (Williams 2010).

Cognitive Behavioural Therapy

Sleep disturbances, depression, fear and decreased cognitive responses such as poor memory and concentration often present in people with chronic pain. For this reason, CBT fits into the SM model. CBT can be described as being based on the principle that thought processes influence feelings and behaviors. Identifying negative thought processes and learning to replace them with positive ideology and strategies is central to CBT (Backman 2006). Strategies to enhance SE, manage stress and negative emotions, develop knowledge, skills, and problem solving are taught using goal setting, education, relaxation, and cognitive techniques such as self-talk, distraction, visualisation and coping techniques (Backman 2006).

Being able to identify differences in an individual's pain perception and subsequent reactions to pain is important in the effective delivery of treatment (Eccleston 2001). People with chronic pain tend to become excessively attentive to the prospect of pain and the spinal cord becomes sensitised causing increased excitability and larger receptive fields (Kosek and Ordeberg 2000). This continual attention to pain has the potential to result in increased levels of disability and distress. It also translates to a fear of performing certain activities, because of the expectation of pain and ultimately results in a chronic decrease in activity associated with an increase in disability (Eccleston 2001). Encouraging a gradual increase in activity in combination with CBT promotes an improved sense of control and SE,

reduced pain, and improved mood (Turner-Stokes, Erkella-Yuksel et al. 2003). Goal setting, a common component of SM, will often include a gradual increase in activity in tandem with CBT techniques.

The treatment of chronic pain with CBT is complex, lengthy, and variable, but never the less, an effective therapy (Morley, Eccleston et al. 1999). Self-management and CBT can be effective treatments in reducing pain, disability and distress, however, these therapies are associated with a significant drop out rate with certain individuals (Kerns and Rosenberg 1999). It is suggested that people with chronic pain go through different stages of receptiveness, and that this will identify those people more likely to respond to SM and CBT. Those who are not at a receptive stage will be less likely to participate or respond to the therapy and are more likely to drop out.

Elements of SM programs

SM programs are generally based on a number of principles. These include the fact that they are best conducted in groups, with emphasis placed on goal setting, self regulation and problem solving.

Group Effect on Self-efficacy

Bandura (1994) suggested that the strength of groups can be a unifying factor so that improvements can be made on a united front. The collective beliefs of group efficacy will influence what the group chooses to do, how much effort the group puts into achieving a goal, their endurance when collective group efforts fail to produce quick results, and their likelihood of success (Bandura 1994).

This is an important concept in the context of SM, which in terms of arthritis is usually in a group format. Not only does SE affect an individual's success, it also has a powerful impact on group dynamics and the influence the group has on each individual within that group (Bandura 2001). Group dynamics are such that they will effect an individual's performance and the group's

enthusiasm will encourage people to achieve more than they may have on an individual basis (Choi, Price et al. 2003).

Goal Setting

Goal setting is designed to enable completion of small tasks or behaviour changes. As goals are achieved there is a heightened sense of wellbeing and improved SE. The combination of goal setting and group persuasion is likely to have a positive effect on SE provided the goals are achievable. The content of SM programs can be designed to promote situations where success is likely, thus enhancing feelings of triumph and consequently SE (Bandura 1994). Goal setting is an important factor in SM as it encourages health related behaviour as part of the process, with the associated achievement of goals enhancing SE.

Self-Regulation

Self-regulation is a concept that is also integral to SM. It underlies the efficacy of SM. Since SM is aimed at making people their own health managers, self-regulation plays an important role because at some point people have to incorporate health information and disease management into their own personal goals (Karoly 1993). Self-regulation is very much involved with the process of striving for and achieving goals (Maes and Karoly 2005). It is at this point that behavioural changes take place.

SM requires the exercise of motivational and self-regulatory skills which includes self-monitoring of health-related behaviour and feelings of well being, developing goals and the strategies to achieve them, and the resolution to maintain the achievement of these goals long term (Bandura 2005). Maes and Karoly (2005) describe goal setting as setting the stage for self-directed change and implementation strategies that convert goals into productive actions, with maintenance strategies that help to sustain achieved behavioural changes (Maes and Karoly 2005). Teaching self-regulated motivation and activities through goal setting encourages attempts for higher

achievements (Bandura 1999). Goal setting motivates progression in the right direction, rather than staying in the comfort zone.

Self-observation is an important part of self-regulation. It serves to provide information necessary for setting goals and it allows evaluation of progress towards that goal (Bandura 1991). To achieve behavioural change it is essential to reflect and observe behaviour and assess the progress attained towards the selected goal. A comparison is then made, usually with the achievements of others or to the group. Past attainments will have some influence on SE, but usually in terms of the goal being to improve on the past achievement (Bandura 1998). The achievement will need to involve some effort, otherwise it will be undervalued and little effort will be expended. This self-regulation has the effect of providing incentive for behaviour and setting the standard for the goal. It helps to motivate people to continue to set more challenging goals.

Problem Solving

Lorig (2003) in her overview of SM education describes chronic illness as being problem orientated. This being the case, problem solving is an important component of SM programs (Lorig and Holman 2003). Problem solving involves identifying problems, making decisions, taking appropriate actions, and altering these actions as circumstances change. It is seen as an essential part of the SM process that actively involves both education and treatment (Toobert and Glasgow 1991). Successful problem solving skills build the resilience necessary to overcome obstacles and thus enhances SE.

Summary

The prevalence of chronic disease is increasing as the population ages. OA of the knee is a widespread chronic condition and one of the leading causes of disability (Walker-Bone, Javaid et al. 2000).

OA affects 1.62 million Australians (Access Economics 2007) and the prevalence over the age 65 years is 19% in men and 32% in women

(Australian Institute of Health and Welfare 2005). As there is no cure for OA, its management is primarily concerned with controlling the pain and improving function and health-related quality of life.

The burden of chronic disease impacts heavily on health expenditure and the shift towards patients having responsibility for their own management has evolved into an increasing acceptance of SM programs. It encourages a transfer of responsibility from health professionals to the individual (Newman, Mulligan et al. 2001; Fries, Lorig et al. 2003; Solomon and Lee 2003). Self-management is considered to be beneficial in the management of chronic illnesses including OA (Lorig, Sobel et al. 2001; Hootman, Sniezek et al. 2002).

Self-management models vary according to the chronic disease. Some depend on health professionals for leadership and others utilize lay leaders. Stanford University's ASMP (Stanford Patient Education Center ; Lorig, Mazonson et al. 1993) is considered to be the gold standard for arthritis SM despite the limited nature of the supporting evidence (Warsi, LaValley et al. 2003; Chodosh, Morton et al. 2005). Lay leaders who are considered to be experts, as many of them have chronic conditions themselves, deliver ASMP programs. Such programs are necessarily based on generic content thus are not disease specific. In addition, participants in any given group are likely to have different arthritic conditions.

Recommendations for future SM have included the use of health professionals (Taylor and Bury 2007; Rogers, Kennedy et al. 2008) and the inclusion of disease specific education to be incorporated into SM constructs (Hill, Mangovski-Alzamora et al. 2009).

This thesis will introduce a new SM program that is disease specific and utilizes the knowledge and skills of health professionals for program delivery. This SM program is designed for people with OA of the knee and is known as the OAK Program. Chapter 3 contains the publications associated with the examination of the value of the OAK Program.

CHAPTER 3

Publications

The four papers that describe the studies that form the basis of this thesis are presented in this chapter. Two of these papers have been published and the other two have been submitted for publication. Papers 1 and 3 described the protocol of the two studies and Papers 2 and 4 present the results.

Study 1 (Papers 1 and 2) examined the OAK Program versus a no treatment control group. Study 2 (Papers 3 and 4) tested the OAK Program against an established SM program, the ASMP.

The two studies were carefully designed so that

1. The groups being compared were homogeneous. That is all participants had a diagnosis of OA of the knee. This is an important point as in previous published studies of SM programs for arthritis, little attention has been paid to the diagnosis of arthritis among participants.
2. Participants were randomized to groups.
3. Assessors were blind to group allocation and used the same standardized assessment tools.
4. Follow-up was for an extended period of time. For Study 1, the follow-up was for six months and for Study 2, the follow-up was for 12 months. The extended follow-up period has not previously been described in the literature.
5. In both Study 1 and 2, the OAK Program was delivered by health professionals. In Study 2, in keeping with the protocol of the ASMP, the program was led by lay leaders. This provided the opportunity to compare the effect of leaders with different attributes.

Because of the requirements of publication, the introductions and background sections of the papers tend to contain some repetition of information. The results and discussion sections of Papers 2 and 4 clearly report the outcomes of the studies.

The contribution of co-authors is clearly stated at the end of each paper.

PAPER 1

Study 1 Protocol Paper

Citation: Coleman, S. Briffa, NK. Carroll, G. Inderjeeth, C. Cook, N. McQuade, J. (2008). "Effects of self-management, education and specific exercises, delivered by health professionals, in patients with osteoarthritis of the knee." BMC Musculoskeletal Disorders 9: 133.

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Study protocol

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Effects of self-management, education and specific exercises, delivered by health professionals, in patients with osteoarthritis of the knee

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Abstract

Background: An education self-management program for people with osteoarthritis (OA) of the knee was designed to be delivered by health professionals, incorporating their knowledge and expertise. Improvement in quality of life, health status and pain in response to this program has previously been demonstrated in an uncontrolled pilot study. To more rigorously test the effectiveness of the program we will undertake a randomised controlled trial of people with OA of the knee offering specific self-administered exercises and education, in accordance with the principles of self-management.

Aim: To determine whether an education self management program for subjects with Osteoarthritis (OA) of the knee (OAK program) implemented by health professionals in a primary health care setting can achieve and maintain clinically meaningful improvements compared standard medical management in a control group.

Methods: The effects of standard medical management will be compared with the effects of the OAK program in a single-blind randomized study.

Participants: 146 male and female participants with established OA knee will be recruited. Volunteers with coexistent inflammatory joint disease or serious co-morbidities will be excluded.

Interventions: Participants will be randomized into either intervention or control groups (delayed start). The intervention group will complete the OA knee program and both groups will be followed for 6 months.

Measurements: Assessments will be at baseline, 8 weeks and 6 months. SF-36, WOMAC and VAS pain questionnaires will be completed. Isometric quadriceps and hamstring strength will be measured using a dynamometer; knee range of movement using a goniometer; and physical function will be determined by a modified timed up and go test. Data will be analysed using repeated measures ANOVA.

Discussion: While there is evidence to support the effectiveness of SM programs for people with hypertension, diabetes and asthma, the evidence available for treatment of arthritis remains equivocal. The aim of this study is to determine the effectiveness of a disease specific self-management program for people with OA knee.

The study design includes all the important features of a clinical experimental study to minimize bias so the results of the study will provide a high level of evidence. People with OA of the knee have identified pain and problems with daily activities as the most important problems associated with their condition. The outcome measures selected specifically address these issues and have demonstrated validity and are responsive within the range of change expected in response to the intervention. Hence the results of the study will reflect their priorities.

The results of the study will provide evidence to guide clinicians and funding bodies seeking to establish priorities regarding the provision of this disease specific program.

Trial registration: ACTR number: 12607000080426

Background

Self-management is a primary care intervention that has become a popular component of management in a number of chronic conditions including arthritis. Unlike traditional patient education programs, self-management programs aim to achieve more than the provision of information to increase knowledge. They also aim to change health behavior and health status, teaching patients to identify and solve problems, set goals and plan actions [1].

Numerous self-management programs have been developed for different health conditions. Various models have been employed including individual and group-based programs that may be disease specific or generic [2]. Face-to-face interaction with health professionals is an important component of some programs, whereas trained lay leaders, usually presenting scripted information, deliver others.

There is a considerable body of research evaluating self-management programs. Reviews and meta-analyses [3,4] have shown that patient self-management education programs can significantly improve knowledge, compliance behaviours, and health outcomes, however the effectiveness differs between programs and disease states.

One systematic review of self-management interventions for a number of chronic diseases, found a trend towards a small benefit from arthritis programs, but the results were not significant and there was a suggestion of publication bias [2]. Many of the existing arthritis self-management programs are designed to cater for participants with any form of arthritis. Examples of this approach are the Chronic Diseases and Arthritis Self-Management programs (ASMP) developed at Stanford University [5,6]. These programs are also delivered in a group setting but they are led by trained lay tutors. They have a more generic approach as they are catering for participants with a variety of different musculoskeletal diseases in the one group. This approach may be cheaper to deliver but cost-effectiveness is yet to be established [7,8].

The ASMP has been tested widely with the majority of studies conducted in the USA or UK. Many, but not all of these studies have found the program to be effective. Overall, Warsi et al (2004), in their systematic review of self-management interventions for various chronic diseases, found a trend towards a small benefit from arthritis programs, the majority being ASMP or ASMP derivatives, but the results were not significant and here too it was suggested that there was publication bias [2].

We hypothesised that a program designed for a specific diagnostic group may be more effective. We considered a program of this nature would be justified for more prevalent conditions such as osteoarthritis of the knee.

Accordingly, we developed a self-management program for people with osteoarthritis of the knee. The program was designed to be delivered by health professionals. Strategies for pain management; the benefits of different types of exercise (strength, aerobic, flexibility, balance); and approaches for falls prevention were included. In keeping with a social cognitive theory approach, individual problem identification, goal setting and action planning were encouraged to facilitate improvements in self-efficacy. This program was tested in an uncontrolled quality assurance study. The results indicated improvement in pain, quality of life and physical function [9]. The purpose this study was to more rigorously test the program in a randomized controlled study.

Methods

Aim

To compare the effectiveness of an osteoarthritis of the knee self-management education program delivered by health professionals with a control group, as determined by improvements in pain, quality of life and physical function.

Study Design

A two group randomized, controlled repeated measures study design will compare the osteoarthritis of the knee program (OAK) with a similar group of control participants. Independently of the study all participants will be able to receive standard medical management of OA knee. In addition, the intervention group will participate in a disease specific knee osteoarthritis self-management program (OAK). Blinding of participants will not be possible due to the nature of the intervention; however, assessors will be blinded to group allocation. The OAK program will be conducted in a community setting at Arthritis Western Australia.

Hypothesis

People with osteoarthritis of the knee who complete the OAK Program will report improved quality of life, improved knee function and decreased pain compared with those managed conventionally.

Ethical Issues

This study has been approved by the Human Research Ethics Committee at Curtin University of Technology (HR141, 2002). All participants will provide written informed consent prior to randomisation. Data access and storage will be in keeping with National Health and Medical Research Council guidelines, as approved. License agreements have been obtained for SF-36 Questionnaire and WOMAC Questionnaire. This trial is registered with the Australian and New Zealand Clinical Trial Registry, number: 12607000080426.

Subjects

146 participants with established OA of one or both knees will be recruited into the study. As the OAK program is generally provided as a clinical service, subjects will be recruited from among people presenting to enroll in the OAK program. The operational definition for OA knee is diagnosis by a medical practitioner based on either clinical examination or radiological evidence. Disease severity is not a selection criterion. Exclusion criteria will be rheumatoid arthritis or other inflammatory joint disease; knee surgery planned within 6 months of commencing the study; physical impairments that preclude full participation; inability to communicate in English within a group setting or aged ≤ 18 years (Table 1). During the recruitment phase the program will be actively promoted to general practitioners and rheumatologists through professional societies, and to the general public through advertising and media coverage.

Volunteers for the study will be randomized to an intervention group (immediate start) or a control group (delayed start). As there is evidence that SM is an effective addition to usual care [5,10], all volunteers randomized to the control group will be offered the intervention at the completion of the 6-month control period.

Group allocation

Volunteers will be randomized in blocks to ensure manageable numbers for intervention groups. Pre-prepared cards indicating group assignment will be placed in sealed opaque envelopes and drawn as a lottery by a third party for allocation to treatment groups. In order to ensure optimum group sizes, allocation will not take place until a whole block has been recruited

Intervention

The OAK program will be conducted over a 6-week period enabling participants to incorporate and consolidate information learned from week to week. In addition to the weekly sessions, participants will be given printed information relevant to the course component discussed each week. Program leaders will be health professionals including nurses, physiotherapists, and occupational therapists that have the knowledge and skills to present information on disease specific topics and accurately respond to complex questions. It is necessary that health professionals who deliver this program meet minimum musculoskeletal knowledge requirements. The fidelity of the OAK program will be maintained by the use of a facilita-

Table 1: Eligibility criteria

Inclusion criteria	Exclusion criteria
English speaking	Co-existing inflammatory arthritis
Aged 18 years or over	Serious co-morbidity
Diagnosis of OA (X-Ray or clinical Dx)	Scheduled knee replacement in < 6 months
Referral from GP or Specialist	Cannot meet program time-points
Able to meet program requirements	

tor's manual with modules for program delivery each week.

To facilitate optimum group dynamics, the target group size will be 12 participants, although this may vary from 8 to 16 depending on recruitment and randomisation. The program approach is holistic and will not exclusively focus on one aspect of care. Self-management constructs will be employed to promote behavioral changes that will be aimed at optimizing participants' health status. Goal setting and the development of strategies to achieve these goals long term [11] will be emphasized in the program. Participants will be encouraged to set their own goals related to health areas that they identify as requiring improvement.

Topics that will be covered in the weekly sessions include:

• Pain management strategies (cognitive and pharmaceutical)

• Joint protection

• Fitness/exercise

• Correct use of analgesia/medications

• Balance/falls prevention/proprioception

• Cognitive techniques

• Pathophysiology

• Nutrition/weight control

• Self-management skills

• Team approach to health care

• SMART goals (Specific, Measurable, Achievable, Realistic, Time-framed)

Assessments and Procedures

Assessments will be performed by 2 physiotherapists blinded to group allocation; conducted one week prior to the first self-management session (baseline) and on the week following the sixth and final session (week 8). The physiotherapists performing assessments will have no contact with the participants other than during the assessment sessions and will not participate in facilitation of the program. Participants will be assessed by the same physiotherapist whenever possible to ensure consistency.

Members of the control group will also attend assessments at baseline, and week 8. All volunteers will be assessed again 6 months after randomisation. In keeping with intention to treat principles, all participants will be encouraged to attend for follow-up measurements regardless of level of attendance at the self-management intervention. Self reported questionnaires (WOMAC, SF-36, VAS pain) would be mailed out to participants that are unable to attend assessment visits. Program and assessment attendance (at all time-points) will also be collected and collated.

Demographic information will include age, sex, co-morbidities and socioeconomic information. Socio-economic scales will be compiled using "The Index of Relative Socio-Economic Disadvantage" scales [12]. This index provides a weighted value that includes variables that reflect or measure disadvantage. These variables include: low-income, low educational attainment, high unemployment and low skilled occupations.

The dependent variables for the study are listed below.

Primary outcomes

• Health status; measured using the WOMAC Osteoarthritis Index for OA of the knee (WOMAC LK3.0). Also self-administered, the WOMAC assesses pain, stiffness and physical function [13] and can be completed in less than 5 minutes. Two major studies have shown WOMAC pain, stiffness and physical function subscales are valid and the questionnaire is reliable and sensitive enough to detect changes in health status following a variety of interventions [14,15]

• Quality of life; measured using the Short Form 36v1 (SF-36) questionnaire. This 36 item questionnaire is self administered, and can be completed in about 15 minutes [16]. Scores for 8 sub components reflecting both physical and mental status can be generated. Reliability and validity have been established in numerous studies [16,17].

Secondary outcomes

• Active range of motion of the knee joints; measured using a long armed Goniometer [18]. The reliability and validity of the goniometer to measure range of motion has been widely documented for knee flexion and extension [18,19].

• Strength of the hamstrings and quadriceps muscles will be measured using a Mecmesin Force Gauge Dynamometer. The dynamometer will be fixed via an adjustable arm to a portable steel frame and stool. Subjects will sit on the stool with hips and knees flexed to 90 degrees. Isometric strength in flexion and extension will be measured in this position. Each knee will be measured 3 times. The first measurement will be a practice and will be excluded from

analysis. The two subsequent measures will be averaged for analysis.

• Pain will be assessed at weekly intervals from baseline to the 8-week follow-up assessment. (See Figure 1: Study Design Flow Chart). A 10 cm Visual Analog Scale (VAS) anchored at the left with "no pain" and at the right "worst pain imaginable" will be used for this assessment. The VAS is well established in clinical practice and research for measuring pain levels in arthritis populations [20].

• Functional mobility, using a Functional Knee Assessment Test (FKAT) will be assessed using a modification of the "Timed Up and Go" test (TUG). TUG is widely used to assess basic functional mobility in the elderly [21-23]. The test measures the time taken to stand from a chair and walk 6 m, turn around, return to the chair and sit down. For this study the addition of ascending and descending a 15 cm step will be added to the outward walk.

Statistical Power Calculation

A priori power calculations for this study will be based on the quality of life outcome as measured by the SF-36. Sample size was calculated according to guidelines in the SF-36 Users Manual to determine differences in changes over time between the intervention and control groups using a repeated measures design allowing an inter temporal correlation between scores of 0.60 [16]. The pilot study SF-36 data showed an average improvement of 10 points across the eight domains measured. Assuming this level of improvement is achieved in the intervention group and there is no change in the control group and allowing for a 10% drop out rate, the number of participants required per group will be 60 [16]. In the pilot study, there was a drop out rate of 5% over 3 years, so allowing 10% is a conservative estimate. Differences in changes in functional ability measured using the WOMAC, similar in magnitude to those previously documented [24] would also be detectable in a sample of this size.

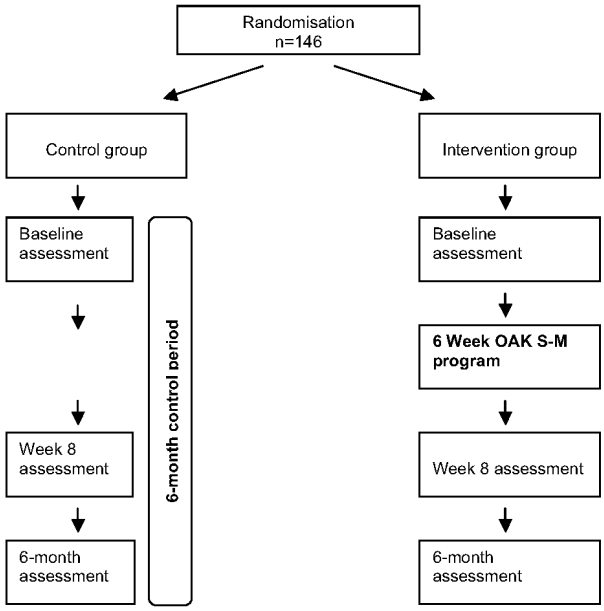

Figure 1
Study Design Flow Chart.

Data Analysis

Data will be analyzed in a blinded manner. Treatment groups will be examined for comparability at baseline. Main comparisons between treatment groups will be performed using an intention to treat analysis. To test the effects of treatment, between group differences in changes over time will be examined using repeated measures ANOVA. Separate analysis will be conducted for each outcome variable. Statistical significance will be inferred at a 2-tailed $p < 0.05$. Results will not be adjusted for multiple comparisons as all outcomes of interest have been nominated a priori and such adjustment would likely render all findings of interest, despite their clinical importance, non-significant.

Discussion

Self-management aims to motivate people to undertake the changes in behavior necessary to improve their lives. The preference of patients to actively manage their condition themselves is well matched to the aim of the multidisciplinary SM program to empower people to manage their condition [25]. People with OA of the knee have identified pain and problems with daily activities as the most important problems associated with their condition. Hence the results of the study will reflect their priorities. The outcome measures selected have demonstrated validity and are responsive within the range of change expected in response to the intervention.

This disease specific self-management program differs from other more generic arthritis programs. Using the skills and expertise of health professionals in a program providing disease specific education and self-management will provide a platform for behavior change that is not feasible with the limited knowledge base of lay leaders. The outcome measures are designed to reflect positive changes in pain, knee function and quality of life (intervention group), compared with those participants that are managed with conventional treatment (control group).

The study design compares the OAK program with the usual management of people with OA in the community. Randomisation to treatment or no treatment groups prevents conscious or unconscious bias [26]. Although blinding of group participants is not possible, the physiotherapists assessing outcome measures will be blinded to group allocation to minimize potential bias [27]. Using an intention to treat design will reflect the way the treatment will perform in the community and reduces the potential bias of drop out or non-compliant participants.

There is insufficient evidence to unequivocally claim that self-management is an effective treatment for osteoarthritis of the knee. The results of the study will provide evidence to guide clinicians and funding bodies to establish priorities regarding the provision of this disease specific program.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SC and KB were responsible for writing the study protocol and drafting the manuscript. GC, CI, NC and JM assisted with study design and provided comments on the drafts and all authors approved the final version of the manuscript.

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PAPER 2

Study 1 Results Paper

(Under review Arthritis Research and Therapy Journal)

A randomised controlled trial of a Self-Management education program for OA of the knee delivered by health professionals.

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ABSTRACT
Introduction. To determine whether a disease specific SM program for people with OA of the knee (the OAK program), implemented by health professionals, would achieve and maintain clinically meaningful improvements in health related outcomes compared with a control group.
Methods. Medical practitioners referred 146 participants with OA knee. Volunteers with coexistent inflammatory joint disease or serious co-morbidities were excluded.
Interventions: Randomisation was to either control or OAK groups. The OAK group completed a 6-week SM program. The control group had a 6-month waiting period before receiving the OAK program.
Measurements: Assessments occurred at baseline, 8-weeks and 6-months. Primary outcomes: WOMAC, SF-36, VAS pain, timed up and go (TUG). Secondary outcomes: knee range of motion, quadriceps and hamstring strength- isometric contraction.
Response to treatment (responders) and minimal clinically important improvements (MCII) were determined.
Results. In the OAK group, VAS pain improved during the 8-week clinic phase, mean (SE) 5.21 (0.30) to 3.65 (0.29) p=<0.001. Responses to treatment were demonstrated in WOMAC pain, physical function and total dimensions. In the SF-36, Physical Function, Role Physical, Body Pain, Vitality and Social Functioning domains improved in the OAK group compared with the control group. The proportion of MCII was greater among the OAK than the control group for all outcomes. Hamstring strength significantly improved in both legs compared with the control group. TUG test, range of motion extension and left knee flexion improved when compared with the control group, although these improvements had little clinical relevance.
Conclusions: Participants in the OAK program recorded significant improvements in pain, quality of life and function at 8-weeks and 6-months compared with a control group.
Trial registration ACTR: 12607000080426

Introduction

Osteoarthritis (OA) is the most common form of arthritis and the third leading cause of life years lost to disability (March and Bagga 2004; Access Economics 2007; Kadam and Croft 2007). It affects 10% of the population and is more common in women than men. By age 65 years 50% of the population will have OA (March and Bagga 2004) and as the population ages, the prevalence of OA is expected to rise. The knee is a commonly affected joint with a prevalence of 30% in people aged 65 years or older.

Self-management (SM) is considered to be an effective strategy in the treatment of chronic illnesses, including OA (Chodosh, Morton et al. 2005). Numerous SM programs have been developed for different illnesses such as diabetes, hypertension, asthma, and arthritis. Various models, both disease specific and generic have been employed including individual, group-based, postal and internet programs (Warsi, Wang et al. 2004). Most arthritis SM programs use lay leaders delivering a scripted program. Face-to-face interaction with health professionals is an important component of some programs, especially where medication compliance is considered relevant.

A number of studies have examined the effectiveness of SM for people with arthritis. One systematic review of SM interventions for various chronic diseases found a trend towards a small benefit from arthritis programs, the majority being the Stanford University's "Arthritis SM Program" (Stanford Patient Education Center) (ASMP) or derivatives of the ASMP, but the results were not significant and a suggestion of publication bias was noted (Warsi, Wang et al. 2004). A comparison of lay leaders versus health professional leaders has also been published (7), however the study required all leaders, both lay and health professionals to deliver the same scripted program, limiting the capacity for the knowledge and skills of the health professionals to be optimally utilised (Cohen, van Houten Sauter et al. 1986). Given the design of the study, it was not surprising that no differences were demonstrated. Despite the popularity of lay led SM programs for arthritis and

taking into account possible cost advantages, Taylor and Bury (2007) suggest that such programs have little or no advantage in terms of improved SE or on the management of chronic illness (Taylor and Bury 2007).

Although lay leaders have the potential to be role models (as they often have musculoskeletal conditions themselves), health professionals with their knowledge and skills can also have a powerful influence as models. Modelling has the potential to transmit knowledge and skills to which people may aspire particularly if the information is perceived to be important and relevant, resulting in behaviour change that is more likely to be maintained long term (Bandura 1994). This platform for behaviour change is constrained because of the limited knowledge of lay leaders.

SE is an integral component of SM, and resilience goes hand in hand with SE. Resilient people tend to have well developed SE and when confronted with an obstacle will see it as a hurdle to overcome rather than an insurmountable problem. Furthermore, they are more likely to persist for longer when repeated problems are encountered (Bandura 1998). Those who attempt and succeed will benefit in terms of improved SE.

Factors influencing SE such as problem solving, pain management, exercise, modelling, social persuasion, weekly goal setting, and cognitive therapy are interconnected. Pain management is important because often people are hesitant to undertake new activities for fear of pain, regardless of whether pain has previously been experienced with that particular activity. Many people with OA rely on medication for pain relief but are reluctant to take medication because of possible side effects. Such people prefer to be aware of the pharmacologic and treatment options available and then decide on a course of management. However, if knowledge about the available options is lacking the treatment choices are more limited and, importantly, this may have an impact on adherence to treatment (Mitchell and Hurley 2008).

The lack of demonstrated benefits related to SM in arthritis suggests an area that requires alternative models of SM to be proposed. This paper reports on

the evaluation of an SM program for people with OA of the knee (the OAK program) designed to be delivered by health professionals.

OAK Program

The OAK program differs from other arthritis SM programs in a number of aspects. It is a disease specific OA SM education program designed for delivery by health professionals. Its theoretical framework uses Social Cognitive Theory (Bandura 2001) to enhance participant's SE and promote long-term changes in behaviour. Results from an uncontrolled quality assurance study of the OAK program were positive in terms of improvement in pain, quality of life, and physical function (Coleman, Briffa et al. 2008a). It was designed specifically for people with OA of the knee and for implementation in a community based setting - thus removing the burden of health care from tertiary institutions. The education component of this program is detailed, so delivery by health professionals is more appropriate than delivery by lay leaders. Principles and theories of SM are used to promote behavioural change in a multifactorial format. In particular, exercise and disease coping strategies are promoted within a SM construct as a means to improve quality of life, general health and to reduce pain.

Health professionals delivering the program are required to have the necessary knowledge and skills to present information about OA of the knee and respond accurately to complex questions. The fidelity of the OAK program is maintained by the use of a facilitators' manual with modules for program delivery each week designed specifically to maintain consistency and accuracy of the information delivered.

The OAK program is conducted in a group setting with six weekly sessions of 2.5 hours each. Attendance is voluntary, however participants are encouraged to attend all sessions. The program is designed so that participants will progress over time by incorporating and consolidating information learned from week to week. In addition to the weekly sessions, participants are given printed information relevant to the course component

discussed each week. To facilitate optimum group dynamics, the target group size is 12 participants.

The program takes an holistic approach including multiple aspects of care:

- OA – explanation and implications;
- SM skills (goal setting, problem solving, modelling, positive thinking, improving SE);
- medication (type, interactions, current trends);
- correct use of analgesia (use of, therapeutic dosing, types of analgesia, side effects);
- pain management strategies (cognitive and pharmacological);
- fitness and exercise (strength, flexibility, aerobic and balance);
- joint protection;
- nutrition and weight control;
- falls prevention - balance/proprioception, environmental risks, polypharmacy, and
- coping with negative emotions. Watch caps and punctuation in such a list.

People with OA may initially resist physical activity due to discomfort, fear of pain, or previous advice to avoid exercise (Hootman 2003; Bennell and Hinman 2005). Many believe that exercise will result in bone and cartilage loss and are therefore resistant to exercise in general (Bennell and Hinman 2005), yet avoidance of activity is known to contribute to disability long term (Steultjens, Dekker et al. 2002). The OAK program includes general information about benefits of exercise and specific advice on joint protection during exercise for those with OA of the knee. The program aims to maximize the benefits of physical activity and promote long-term adherence to an exercise regimen by using structured exercise participation that is linked to weekly "SMART" goals (Siegert, McPherson et al. 2004) (**S**pecific, **M**easurable, **A**ttainable, **R**ealistic, **T**ime bound). The program offers the added reassurance that health professionals are on hand to give advice, and the group dynamics offers incentive for participants to comply and maintain the exercise regimen. Participants' success with meeting goals each week

increases SE (Roos 2002), which is the strongest and most consistent predictor of physical activity behaviour and its maintenance long term (Eyler 2003). Although exercise features strongly in the OAK program, it is not an exercise school. Exercise is only one component and it is up to each individual to decide how much emphasis they will give to exercise from week to week during the program.

Cognitive symptom management strategies are encouraged to help eliminate "negative" symptoms associated with OA. Such negativity not only affects individual symptom control, but also contributes to and exacerbates the symptoms of OA (Kidd, Langford et al. 2007). Guided imagery, relaxation techniques, positive self-talk, and problem solving are taught to participants. These enable them to understand how such influences contribute to their symptoms and provide the necessary skills to prevent them becoming an overwhelming negative influence. Health professionals also use their knowledge to assist participants with problem solving to overcome hurdles and promote resilience (Bandura 2001).

Objective of the Study

To determine whether a disease specific SM program for people with OA of the knee (the OAK program), implemented by health professionals, would achieve and maintain clinically meaningful improvements in health related outcomes compared with a control group.

This study was approved by the Human Research Ethics Committee at Curtin University of Technology (HR141). Data access and storage was in keeping with National Health and Medical Research Council guidelines (Australian Government 2009). License agreements were obtained for the SF-36 and WOMAC questionnaires.

The study design adhered to CONSORT guidelines and intention to treat principles. This trial was registered with the Australia and New Zealand Clinical Trials Registry, no: 12607000080426. The protocol has previously been described in greater detail (Coleman, Briffa et al. 2008b). Amendments to the trial protocol included analysis to determine participant's response to

treatment (responders). This was necessary to meet the requirements suggested in the OMERACT-OARSI guidelines (Pham, van der Heijde et al. 2004). In addition, the proportion of people attaining minimal clinically important improvements (MCII) was determined.

Methods

Study Design

A two group randomised (ratio 1:1), controlled repeated measures study, was used to examine between group differences in change over time. Convenience sampling was employed. The research sample was selected from those who were referred to the program. Suitable candidates were invited to enrol in the OAK program. Those who agreed to participate and provided written informed consent were randomised either to an OAK group (immediate start) or a control group (delayed start). For ethical reasons those participants randomised to the control group were offered the OAK program at the conclusion of the six-month study. Independent of the study, all participants were allowed to continue with standard medical management for knee OA. Figure 1 shows the design of the study and the time points at which the outcome measures were recorded.

Participants

One hundred and forty-six participants (37 male and 109 female) with established OA knee, of mean (SD) age 65 (8) years, were enrolled into the study. Inclusion and exclusion criteria are listed in Table 1. All participants who were recruited from the Perth metropolitan area and immediate surrounds, provided written informed consent prior to enrolment.

Socio-economic status was estimated according to residential postcodes using a method developed by the Australian Bureau of Statistics – “The Index of Relative Socio-Economic Disadvantage” (Australian Bureau of Statistics 2001). The index provides a weighted value with a low index value representing disadvantage and a high index value representing advantage (Table 2).

During the recruitment phase the OAK program was actively promoted to general practitioners, rheumatologists and health professionals through professional societies and to the general public through advertising and media coverage. Invitations were also extended to those people with OA of the knee who made general inquiries to Arthritis Western Australia. The OAK program was conducted at Arthritis Western Australia, a community setting that is close to public transport and has available infrastructure to run the program and co-ordinate the study. This project was funded with in-kind support from Arthritis Western Australia. The research undertaken was independent from the funding body.

Randomisation and Blinding

Participants were allocated to study groups using simple randomisation performed in batches of approximately 24 depending on recruitment success. Once a group of 24 volunteers had been recruited, they were randomised to OAK or control groups. Twenty-four pre-made cards (12 intervention and 12 control) in sealed opaque envelopes were placed in a box. An envelope was drawn from the box by an independent person to determine group allocation. Blinding of participants was not possible due to the nature of the intervention; however, the physiotherapists performing the assessments did not participate in the facilitation of the OAK program so were blind to group allocation. To maintain blinding they were asked not to discuss group allocation with the participants during assessments.

Outcome Measures:

The outcome measures included both primary and secondary measures.

Primary measures.

- Health status; measured using the self-administered WOMAC OA index for OA of the knee (WOMAC LK3.0) (Bellamy 2002; Bellamy 2005).
- Quality of life; measured using the Short Form 36v1 (SF-36) questionnaire (Kantz, Harris et al. 1992; Ware, Kosinski et al. 2002).
- VAS pain (Melzack and Katz 1994; Creamer, Lethbridge-Cejku et al. 1999) was assessed at weekly intervals in the OAK group during the

delivery of the OA knee program from baseline to the 8-week assessment. The control group completed VAS pain scores at baseline and at week 8. (See Figure 1: Study Design Flow Chart).

- Functional mobility was assessed using a modified "Timed Up and Go" test (TUG) (Podsiadlo and Richardson 1991; Vellas, Wayne et al. 1997; Huxham, Goldie et al. 2001). For this study the addition of ascending and descending a 15cm step was added to the outward walk. Two measurements were performed and the average of these measurements was used for analysis.

Secondary measures.

- Range of motion of the knee joints; measured using a long-armed goniometer (Gogia, Braatz et al. 1987; Watkins 1991).
- Isometric strength of the hamstrings and quadriceps muscles; measured at 90 degrees of knee flexion using a Mecmesin Force Gauge Dynamometer (Bohannon 1986). Each knee was measured 3 times. The first (practice) measurement was excluded. The 2 subsequent measures were averaged for analysis.

Statistical Power Calculation

An a priori power calculation based on the quality of life outcome as measured by the SF-36 (Ware, Kosinski et al. 2002) was undertaken. The SF-36 was chosen as it is the least sensitive and requires greater sample size to detect changes in treatment differences with respect to pain and physical functioning in people with OA (Davies, Watson et al. 1999). Sample size was calculated according to guidelines in the SF-36 Users Manual, to determine differences in changes over time between the intervention and control groups using a repeated measures design allowing an inter temporal correlation between scores of 0.60 (Ware, Kosinski et al. 2002). Previously, the OAK program quality assurance study SF-36 data showed an average difference of 10 points across the 8 domains measured (Coleman, Briffa et al. 2008a). Assuming this level of improvement was likely to be achieved in the OAK group and no change in the control group and allowing for a 10% drop out rate, the number of participants required per group would be 60

(Ware, Kosinski et al. 2002). In the quality assurance study, the drop out rate was 5% over 3 years, so allowing 10% was a conservative estimate. Differences in changes in functional ability measured using the WOMAC, similar in magnitude to those previously documented (Fransen 2001) would also be detectable in a sample of this size.

Data Analysis

Data were analysed in a blinded manner using SPSS v17 for Macintosh. Treatment groups were examined for comparability at baseline. Despite randomisation, there were between group differences in severity at baseline. Therefore baseline values (as recorded in Table 2) were used as covariates in the analyses (Overall and Ashby 1991). This has the effect of the pre-intervention mean (SE) values being the same at baseline in both groups. Main comparisons between groups were performed using an intention to treat analysis. All participants were encouraged to attend follow-up measurements regardless of the level of attendance. Where data were missing the previous value was carried forward. To test the effects of treatment, between group differences in changes over time (baseline, 8-weeks and 6-months) were examined using repeated measures ANCOVA. A separate analysis was conducted for each outcome variable.

For secondary analyses, a favourable response to treatment (responder) was as defined in the OMERACT-OARSI criteria (Pham, van der Heijde et al. 2004). We used scenario D: An improvement of ≥50% and an absolute change of ≥20 points on a 100 point scale in pain or function, OR an improvement of at least two of the following: An improvement of ≥20% and an absolute change of ≥10 in two of pain, function and global health. However as patient's global health was not recorded in this study only the pain and function section of the second alternative were available.

Furthermore, the proportion of participants achieving MCII independently in health status, quality of life, pain, and the TUG test were computed for each group at each observation time.

The criteria for minimal clinically important improvements are (Tubach, Ravaud et al. 2005):

- Health status using WOMAC physical function (0 to 100)
    - absolute change: –9.1
    - percent change: –26.0
- VAS Pain
    - absolute change: –1.99
    - percent change: –40.8
- Quality of life using SF-36 (pain and physical function domains)
    - absolute change: +5 points
- TUG
    - percent change: -9

The proportion of participants achieving MCII and responder criteria was computed for each group at each observation time. Chi-square test was used to examine the effect of the treatment, in terms of the proportion of MCII and responders. Statistical significance was inferred at a 2-tailed $p<0.05$. Results were not adjusted for multiple comparisons as all outcomes of interest were nominated a priori and such adjustment would likely render all findings of interest, despite their clinical importance, non-significant (Perneger 1998).

Results

Table 2 shows the number, characteristics and distribution of all subjects. The male to female ratio was not significantly different between groups (Chi-Square $2.311_{(1,146)}$ $p=0.182$). Sixty-eight participants from each group completed the program and returned for the follow-up assessments at 6-months. All participants included in the analyses attended at least 4 of the 6 SM sessions. The mean (median) attendance in the OAK group was 5.77 (6) sessions. The reasons cited for withdrawal were overseas relocation, work, family, and time commitments, and not being randomised to the OAK group. Participants from the highest socio-economic group were over represented and approximately 90% had co-existing disease (Table 2).

Mean Differences

Primary measures

WOMAC pain, physical function and total scores improved significantly more in the OAK group when compared with the control group (Table 3). The advantage in between-group difference in change was evident at post-treatment and 6-months follow-up in the physical function and total scores, however by 6-months the improvement in pain was comparable between groups.

There were improvements from baseline to 8-weeks in the SF-36 scales Physical Function, Role Physical, Body Pain, Vitality and Social Function in the OAK group compared with the control group. These differences were maintained at 6-months (Table 3).

In the OAK group, VAS pain decreased 30% during the 8-week intervention phase [mean (SE) 5.21 (0.30) to 3.65 (0.29) p=<0.001], while the control group had a 17% increase in pain [5.27 (0.30) to 6.19 (0.32) p=<0.001] during the same period. The difference in the mean change between groups, baseline to week eight, was 2.54 cm (95%CI 1.66 to 3.41).
TUG results showed a significant improvement in the OAK group compared with the control group post- intervention and at 6-months, however the improvement was small (Table 4) (van Iersel, Munneke et al. 2008). An MCII for TUG was observed in 3 times as many OAK group participants as control group participants at 8-weeks (OAK: 46 and control group: 15), however this ratio was appreciably lower at 6-months (OAK: 38 and control: 26).

Secondary measures
Hamstring strength improved in both right and left legs in the OAK group compared with the control group. In the right hamstrings there was a 34% improvement post-intervention and a 29% improvement at 6-months. In the control group, improvements of 10% post-intervention and 14% at 6-months were achieved. Similar improvements were observed in the left hamstrings (Table 4). Despite the significance of these results, they have little clinical meaning due to the limited magnitude of the improvement. There was no significant difference between groups in quadriceps strength in either left or right legs.

Small increases in range of motion were observed. Extension in both knees, and flexion in the left knee in the OAK group improved significantly compared with the control group, however these improvements also were of questionable clinical significance due to the magnitude of the improvement.

Responders

Following the intervention, the proportion of responders at 8-weeks in the OAK group was more than 3 times that of the control group (Table 5). At this post-treatment assessment 26 people from the OAK group and 8 from the control group were classified as responders according to the pre-specified criteria for response to treatment (Tubach, Ravaud et al. 2005). There were more responders in the OAK group than in the control group at 6-months, however the proportion of responders was lower in both groups and the difference between groups was not statistically significant.

Minimal Clinically Important Improvements

The OAK group had a greater proportion of MCII's in all outcome measures at all time-points when compared with the control group. The differences were significant for all variables apart from SF-36 pain at 8-weeks and 6-months and physical function at 6-months (Table 5). The proportion of MCII's between the OAK and control groups was greatest immediately post intervention. In the OAK group approximately 3 times as many participants were observed to achieve a MCII compared with the control group at 8-weeks and almost twice the number at 6 months.

Discussion

In this RCT we have demonstrated that participants in a SM program specifically designed for people with OA of the knee and delivered by health professionals experienced improvements in a number of health domains that people with OAK have identified as important problems associated with their condition (Tallon, Chard et al. 2000).

SM aims to motivate people to undertake the changes in behaviour necessary to improve their condition. The priorities of people with OA knee have been identified as problems with pain and activities of daily living and their preference is to actively manage their condition (Tallon, Chard et al. 2000; Mitchell and Hurley 2008). The OAK program was designed as a community based SM education program that aims to improve pain, function and quality of life and empower people to address these preferences with the support of health professionals who have expertise in this area. The OAK program incorporates education with an emphasis on OA related information and the benefits of exercise within SM constructs to promote improved SE and changes in behaviour. Utilising the knowledge and skills of health professionals is a chief component of the OAK program because knowledge is an important part of SE in that no amount of confidence will produce success unless the required knowledge and skills are present (Pajares 2002).

The mechanisms involved in successful SM are not well understood. The highly structured nature of the intervention may be important and other non-specific mechanisms such as group dynamics may be contributory. Nevertheless, there appears to be consensus that the efficacy is likely to be due at least in part to increased adherence to medications (Chodosh, Morton et al. 2005). It should be noted that in the OAK program, educational material concerning pharmacological therapy and pain relief are included in the syllabus.

WOMAC and SF-36 questionnaires are both tools that can demonstrate improvements in pain and in patients overall health status (Angst, Aeschlimann et al. 2001), however in people with OA, WOMAC is more sensitive to change in pain and physical function than SF-36 (Davies, Watson et al. 1999). Improvements in pain scores demonstrated in the VAS were reflected in WOMAC and SF-36 in the OAK group when compared to the control group and they were maintained to 6-months. Similarly, a greater proportion of responders were demonstrated at both 8-weeks and 6-months in the OAK group, when compared with the control group.

Determining the value patients place on improvements in pain can be difficult. In response to rofecoxib or ibuprofen improvements of 9% to 10% in WOMAC scores were perceptible to patients with OA knee (Bellamy, Bell et al. 2005). The OAK group demonstrated improvements in WOMAC pain of 23% pre to post intervention and 13.7% pre intervention to 6-months. By contrast at the same time-points the control group had improvements in WOMAC pain of 2.3% and 7%.

One limitation of the study was that it compared a treatment program with a no-treatment control group. Therefore the only blinding that could be maintained was assessor blinding, an important consequence of which is the risk of reporting, attrition, and other types of bias. In addition, self-reporting of pain may be affected by bias, as patients are keen to "do well" and to please health care providers by reporting an improvement when there may not have been one. Moreover, the perception of the efficacy of the treatment by the health care providers may influence how the patients perceive their pain and result in improved pain rating (Hirsh, Atchison et al. 2005) suggesting that the bias related with no-treatment control groups is generally underestimated (Hrobjartsson and Gøtzsche 2004).

As with pain, there were significant improvements in quality of life and function in the OAK group compared to the control group, with improvements seen in WOMAC and SF-36 maintained to 6-months. Physical improvements were also maintained at 6-months when compared with the control group. Self- reported functional outcome measures tend to be influenced by pain, so it is important to have functional as well as self-reported outcome measures as the combination gives a more realistic appraisal of functional ability than self-reported outcomes alone (Boonstra, De Waal Malefijt et al. 2008).

The control group also demonstrated improvements in many outcomes. It is difficult to explain these improvements other than in terms of patient health care provider interactions at assessments. Patients in untreated control groups may interact with health care providers and Hrobjartsson and

Gøtzsche (2004) suggest that the possibility of patient-provider interaction could have clinically useful effects (Hrobjartsson and Gøtzsche 2004). Within group improvements were evident in WOMAC (stiffness and total scores), SF-36 (physical function, role physical, general health, vitality and role emotional), and TUG over time.

The significant improvements seen in hamstring strength, but not quadriceps strength are difficult to explain. The OAK program is not an exercise school and although participants are encouraged to exercise, the exercises are delivered within a SM format that requires individuals to adopt an exercise regimen that best meets their needs.

These results reflect the improvements seen in a previously reported quality assurance study testing the OAK program (Coleman, Briffa et al. 2008a). The use of a more rigorous study design further strengthens the earlier findings. The combined information should prove useful for planning future models of SM in arthritis and although the use of health professionals as facilitators will add to the costs there is only weak evidence to support SM programs that use lay leaders. Cost analysis was not within the scope of this study. Future research comparing the OAK program with a lay lead SM program will be a useful step in determining the most effective model.

The highest socioeconomic group was over represented in this study. It is possible that the study results may overstate the likely impact on the wider community, as there is the potential that people with higher education levels may have better outcomes. Arthritis WA is located in a middle class area, and previous attempts were made to recruit from lower socio-economic areas, with limited success. Strategies for outer metropolitan and rural clinics were discussed and may be pertinent for future studies. Moreover, self-initiated enrolment may produce a potential bias as those people who volunteer may already be predisposed to SM (Newbould, Taylor et al. 2006; Taylor and Bury 2007).

Conclusions

In participants with OA of the knee, statistically significant improvements in pain, quality of life and function were observed in the group randomised to an OAK intervention program delivered by health professionals, compared to those randomised to a control group. The number of participants achieving MCII and responder criteria at 8-weeks and 6-months in the OAK group compared with the control group adds strength to these findings.

Abbreviations:
OAK: OA of the knee program
MCII: Minimal clinically important improvement
TUG: Timed up and go test
OA: OA
SM: SM
ASMP: Arthritis SM Program

The authors declare that they have no conflicting interests.

Authors' contributions:

SC collected the data. SC and KB were responsible for data analysis and writing the manuscript. GC, CI, NC and JM assisted with study design and provided comments on the drafts and all authors approved the final version of the manuscript.

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Table 1: Eligibility criteria

Inclusion criteria	Exclusion criteria
English speaking	Co-existing inflammatory arthritis
Aged 18 years or over	Serious co-morbidity
Diagnosis of OA (X-Ray or clinical Dx)	Scheduled knee replacement in < 6 months
Referral from GP or Specialist	Cannot meet program time-points
Able to meet program requirements	

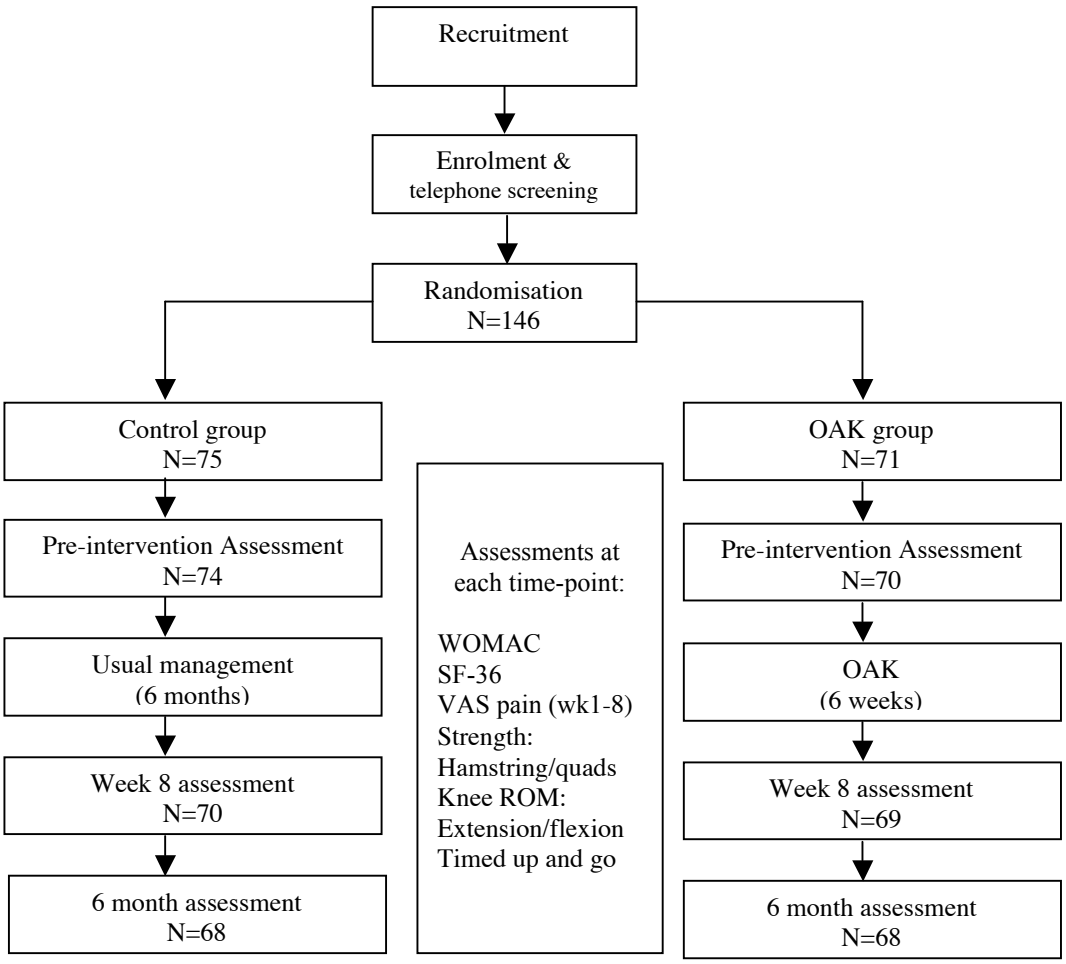

Figure 1: Study Design Flow Chart and evaluation tools used at each assessment. N=number of participants included in the data analyses. This includes values from returned posted questionnaires from non-attendees and last value carried forward for other missing data.

Table 2: Characteristics of participants enrolled in OAK program

	Control	**OAK**
Age mean (SD)	65 (8.7)	65 (7.9)
Gender (M:F)	(23:52)	(14:57)
Socio-Economic Index by Post Code (Australian Bureau of Statistics 2001) Index measured in quintile ranges	Number (%)	
Top 25%	43 (57)	46 (65)
50-75%	10 (13)	9 (13)
25-50%	6 (8)	8 (11)
10-25%	11 (15)	6 (8)
Bottom 10%	5 (7)	2 (3)
Co-existing disease	Number (%)*	
Total number	156	156
Cardiovascular	48 (64)	56 (79)
Gastrointestinal	17 (22)	21 (29)
Musculoskeletal (other than OA knee)	32 (43)	12 (17)
Mental Health	6 (8)	7 (10)
Endocrine	18 (24)	13 (18)
Osteoporosis	8 (11)	8 (11)
Other	27 (36)	39 (55)
None	9 people (12%)	6 people (8.5%)
Multiple coexisting diseases	49 people (65%)	43 people (60%)
Mean (SD) incidence per person	2.39 (1.4)	2.43 (1.65)

* Percentage adds to >100 as some participants have more than one coexisting disease

Unadjusted baseline values Mean (SD) Control and OAK groups

SF-36	Control	OAK	*p* value
Physical Function	43.98 (21.2)	50.41 (22.2)	.078
Role Physical	28.38 (36.6)	40.00 (39.7)	.070
Body Pain	42.00 (19.1)	49.73 (19.0)	.016
General Health	64.81 (17.2)	65.05 (18.4)	.936
Vitality	52.70 (21.0)	55.86 (16.4)	.321
Social Function	69.43 (26.1)	75.54 (22.1)	.133
Role Emotional	57.66 (43.1)	66.19 (42.6)	.235
Mental Health	74.92 (15.1)	75.94 (14.8)	.683
WOMAC Pain	8.00 (3.6)	6.53 (3.7)	.020

Table 3: Results for primary outcomes: WOMAC and SF-36: pre-intervention (baseline), post-intervention (8-weeks) and 6-months. Repeated measures ANCOVA with baseline value of the dependent variable as the covariate; Data are estimated marginal mean (SE) with the mean (95% CI) difference of change between the groups at each time-point.

Variable	#OAK & Control Pre Intervention	OAK		Control		Difference in change between groups		Difference in change between groups	
		8wks	6mths	8wks	6mths	Pre to 8 wks	95% Confidence intervals	Pre to 6 mths	95% Confidence intervals
WOMAC									
Pain*	7.1 (0)	5.5 (0.3)	6.1 (0.3)	7.0 (0.3)	6.7 (0.3)	-1.46	-2.18 to -0.73	-0.49	-1.26 to 0.28
Stiffness	3.6 (0)	3.1 (0.2)	3.1 (0.2)	3.6 (0.1)	3.4 (0.2)	-0.50	-0.91 to -0.08	-0.29	-0.73 to 0.15
Physical Function*	24.1 (0)	19.1 (0.7)	19.9 (1)	24.4 (0.7)	23.4 (0.9)	-5.55	-7.38 to -3.31	-4.35	-6.20 to -0.91
Total*	34.9 (0)	27.7 (1.0)	29.2 (1.2)	34.9 (1)	33.3 (1.2)	-7.23	-9.98 to -4.49	-4.08	-7.47 to -0.68
SF-36 (0 to 100)									
Physical Function*	48.0 (0)	54.1 (1.4)	54.2 (1.9)	48.5 (1.4)	48.5 (1.9)	5.61	1.84 to 9.37	5.67	0.40 to 10.93
Role Physical*	35.7 (0)	47.9 (4.0)	46.0 (4.8)	30.8 (4.0)	38.6 (4.8)	17.06	5.90 to 28.21	7.37	-5.93 to 20.67
Body pain*	46.3 (0)	51.2 (1.9)	50.8 (2.1)	44.0 (1.9)	44.8 (2.2)	7.19	1.93 to 12.44	6.06	0.04 to 12.07
General Health	65.8 (0)	69.2 (1.3)	69.6 (1.7)	67.1 (1.3)	66.0 (1.7)	2.11	-1.45 to 5.67	3.59	-1.19 to 8.37
Vitality*	54.7 (0)	59.0 (1.5)	60.7 (1.7)	53.0 (1.5)	56.0 (1.8)	6.02	1.87 to 10.16	4.72	-0.11 to 9.55
Social Function*	73.8 (0)	83.0 (2.2)	77.8 (2.6)	72.3 (2.1)	72.7 (2.6)	10.72	4.81 to 16.62	4.07	-2.08 to 12.22
Role Emotional	61.7 (0)	73.7 (3.9)	70.8 (4.5)	68.5 (3.9)	69.4 (4.5)	5.18	-5.64 to 16.00	1.35	-11.06 to13.76
Mental Health	75.8 (0)	77.0 (1.3)	78.5 (1.5)	74.9 (1.3)	74.7 (1.5)	2.08	-1.42 to 5.58	3.85	-0.21 to 7.91

*p value <0.05 for baseline to 6months.
#Pre-intervention values are the same in both groups when using the baseline as a covariate

Table 4: Results for secondary outcomes: quadriceps, hamstring strength, knee joint range of motion and TUG.
Pre-intervention (baseline), post-intervention (8-weeks) and 6-months using repeated measures ANCOVA with baseline value of the dependent variable as the covariate; Data are estimated marginal mean (SE) with the mean (95% CI) difference of change between the groups at each time-point.

Variable	#OAK & Control Pre Intervention	OAK		Control		Difference in change between groups		Difference in change between groups	
		8wks	6mths	8wks	6mths	Pre to 8wks	95% Confidence intervals	Pre to 6mths	95% Confidence intervals
Muscle Strength (kg)									
L Quadriceps	18.9 (0)	20.3 (0.5)	19.6 (0.7)	18.6 (0.5)	18.1 (0.7)	1.65	0.34 to 2.95	1.58	-0.31 to 3.47
R Quadriceps	18.0 (0)	19.6 (0.5)	18.9 (0.7)	17.8 (0.5)	18.2 (0.7)	1.79	0.33 to 3.24	0.66	-1.37 to 2.69
L Hamstring*	8.0 (0)	10.1 (0.3)	9.5 (0.4)	8.6 (0.3)	8.8 (0.4)	1.47	0.63 to 2.30	0.74	-0.31 to 1.79
R Hamstring*	7.6 (0)	10.2 (0.3)	9.8 (0.4)	8.4 (0.3)	8.7 (0.4)	1.80	0.89 to 2.70	1.18	0.06 to 2.29
Range of Motion (degrees)									
L Knee Flexion*	125 (0)	126 (0.8)	126 (0.9)	123 (0.8)	123 (0.9)	2.80	0.58 to 5.02	2.26	-0.32 to 4.86
R Knee Flexion	123 (0)	123 (0.9)	121 (0.9)	121 (0.9)	121 (0.9)	1.56	-0.90 to 4.02	0.02	-2.53 to 2.57
L Knee Extension*	-4 (0)	-4 (0.3)	-4 (0.5)	-4 (0.3)	-3 (0.5)	0.1	-0.72 to 0.88	-1.39	-2.71 to -0.06
R Knee Extension*	-4 (0)	-4 (0.3)	-5 (0.5)	-5 (0.3)	-3 (0.5)	0.9	-0.03 to 1.78	-1.18	-2.63 to 0.26
Timed up-and-go* (s)	12 (0)	10 (0.2)	10 (0.2)	11 (0.2)	11 (0.2)	-1.3	-1.81 to -0.86	-0.72	-1.35 to -0.08

**p* value <0.05 for baseline to 6months
#Pre-intervention values are the same in both groups when using the baseline as a covariate

Table 5. MCII and participant responders and using OMERACT-OARSI criteria (Tubach, Ravaud et al. 2005) pre and post intervention and at six-months

	Pearson's Chi-Square		Number with MCII	
Pre-intervention to 8 weeks			OAK	Control
WOMAC PF absolute	10.84 $_{(1, 141)}$	p=0.001	25	9
WOMAC PF percent	19.34 $_{(1, 141)}$	p=<0.001	29	7
SF-36 Physical Function	8.34 $_{(1, 140)}$	p=0.006	40	23
SF-36 Pain	1.38 $_{(1, 139)}$	p=0.265	23	17
VAS pain absolute	15.95 $_{(1, 139)}$	p=<0.001	27	7
VAS pain percent	17.37 $_{(1, 139)}$	p=<0.001	25	5
Responders	13.59 $_{(1, 141)}$	p=<0.001	26	8
Tug	28.87 $_{(1, 139)}$	p=<0.001	46	15
Pre-intervention to 6 months				
WOMAC PF absolute	3.87 $_{(1, 135)}$	p=0.057	24	14
WOMAC PF percent	4.37 $_{(1, 135)}$	p=0.043	27	15
SF-36 Physical Function	2.93 $_{(1, 136)}$	p=0.122	40	29
SF-36 Pain	0.95 $_{(1, 135)}$	p=0.384	31	25
Responders	2.58 $_{(1, 135)}$	p=0.123	22	14
TUG	5.10 $_{(1, 132)}$	p=0.036	38	26

Summary of the OAK Program and the ASMP

The following publication paper introduces Study 2 that is a RCT comparing the OAK program with the Stanford University's Arthritis Self-Management Program (ASMP). In order to understand the differences between these two SM programs, a brief summary of the two programs is provided below.

Similarities between the OAK Program and the ASMP:

Group size

Both SM programs consist of small groups of between twelve and fifteen people depending on recruitment. Previous non-study ASMP courses and the OAK quality assurance study conducted at Arthritis WA have shown that groups of less than eight people do not exhibit the same cohesiveness and group dynamics. Similarly, larger groups become less intimate and have the potential to become unmanageable. Quieter participants tend to become "lost" within larger groups.

Social Cognitive Theory (SCT)

Both SM program use the SCT as their theoretical basis. They both include the following aspects of SCT:

Goal Setting (weekly)

Problem Solving

Guided Imagery

Cognitive Behavioural Therapy

Small group discussion

Both the OAK Program and the ASMP have segments that utilise small groups or pairs of participants. The ASMP has more opportunity for this format than the OAK Program.

Length of program

Both SM programs are run for 2.5 hours per week over 6 weeks as this amount of time is needed to consolidate information learned each week and for behaviour patterns to become established.

Program fidelity

Both the ASMP and the OAK Program have facilitator's manuals and ASMP facilitators are expected to closely adhere to the manual. The OAK Program also has a facilitator's manual however there is more latitude for health professionals to respond to questions on an individual basis since they are required to meet minimum standards of knowledge and expertise for program delivery.

Trained facilitators

Both the ASMP and the OAK Program require leaders to be trained prior to facilitating the programs.

Differences between the OAK Program and the ASMP

The OAK Program:

Exercise

The OAK Program has much more detailed information and a greater emphasis on exercise than the ASMP. It has detailed information on exercise with instruction and demonstration that leads to group participation in practising specific exercises. These are usually strengthening, balance or flexibility exercises that can be practiced in the clinic room. Health professionals are available for individual instruction on technique and also to answer questions and for trouble shooting at subsequent sessions, should problems arise.

The importance of physical activity as well as structured exercise is covered at every session with specific examples and requirements. However, being a SM program, the progression of exercises is solely up to the individual. The health professionals provide information with a selection of exercise choices accompanied by demonstration and follow-up support. The principles of

progressing beyond the comfort zone (with relevance to OA) and adding and consolidating from week to week are discussed and encouraged. Progression is important and the influence of group dynamics, goal setting and problem solving to improve self-efficacy plays an important role. Pain management is an important component of the syllabus because many people are hesitant to undertake new activities for fear of pain.

The importance of balance and proprioception exercise is particularly stressed and different exercises are introduced throughout the 6-week program. Incidental balance exercises are encouraged with the aim of these becoming “habits”. Portions of the day that are otherwise wasted are suggested for balance practice; for example alternate standing on one leg while ironing or washing up (with safety issues being highlighted).

Pain management covers an entire session and includes medication and cognitive techniques. Analgesia and principles of therapeutic dosing to ensure adequate pain relief is achieved, with instruction on the differences between acute pain and chronic pain analgesia dosing regimens are discussed. The hazards of polypharmacy with relation to interaction between multiple medications and the increased risk of falls are also discussed. Strategies for regular review of medications with physicians are included.

Current trends are continually reviewed and updated (for example the current controversy with NSAIDs). Participants have opportunity to ask questions relating to medications, surgical procedures and treatment options. Prescriptive advice is not offered; participants are encouraged to discuss issues with their medical practitioner, however strategies for communicating with health professionals are discussed.

Evidence-based information on “alternative treatments” is discussed with techniques for scrutiny of Internet “information” and suggestions for discerning credible sites that are reputable.

Pathophysiology of OA and OA knee are included in the OAK Program syllabus, with signs, symptoms and disease progression. This information is constructed in a format along with diagrams that is equivalent for a year 9 student to understand. This session includes time for questions and answers.

The ASMP:
Many of the topics covered in the OAK Program are included in ASMP. The crucial difference is the length and depth to which they are discussed. This is appropriate as lay leaders do not have the knowledge and skills of health professionals. The premise of the ASMP is that lay leaders are "experts" since many of them have arthritis themselves and the ASMP is purposely designed to have a general approach to arthritis.

Exercise is discussed at a cursory level. The difference between aerobic, strength and flexibility exercises is highlighted and exercise is encouraged however in general terms with no specific recommendations, instruction or exercise related problem solving. Goal setting is not exercise orientated, unlike the OAK Program.

The ASMP generally has heterogenous groups of participants. People with any musculoskeletal condition may enrol into the program (though this is not the case in Study 2. All participants in both the ASMP and the OAK Program were required to have OA of the knee). The OAK Program requires that all people enrolling into the program must have diagnosed OA of the knee.

The emphasis of the ASMP is more orientated towards a support group dynamic. Every session includes some form of support, either group or pairs of individuals discussing problems that might arise relating to arthritis. In the ASMP, there is more scope for group discussion than in the OAK Program. Participants have greater opportunity for individual problems to be vocalised; the ASMP course content allocating time for this during each session.

The ASMP has much less didactic content than the OAK Program, with more individual and group discussion. In the OAK Program, didactic teaching was necessary for pathophysiology, medication and exercise instruction, with time allocated for questions and group discussion after each topic.

The ASMP encourages partner participation (though partners were not permitted in Study 2). In future OAK Programs, this will certainly be encouraged, however at this stage of testing limiting extraneous influences seemed prudent.

PAPER 3

Study 2 Protocol Paper

Citation: Coleman, S. McQuade, J. Rose, J. Inderjeeth, C. Carroll, G. Briffa, K. (2010). "Self-management for osteoarthritis of the knee: Does mode of delivery influence outcome?" BMC Musculoskeletal Disorders 11(56).

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http://www.biomedcentral.com/1471-2474/11/56

BMC Musculoskeletal Disorders

STUDY PROTOCOL Open Access

Self-management for osteoarthritis of the knee: Does mode of delivery influence outcome?

Sophie Coleman[1,2*], Jean McQuade[2], Jessica Rose[2], Charles Inderjeeth[3], Graeme Carroll[4], N Kathryn Briffa[1]

Abstract

Background: Self-management has become increasingly popular in the management of chronic diseases. There are many different self-management models. Meta analyses of arthritis self-management have concluded that it is difficult to recommend any one program in preference to another due to inconsistencies in the study designs used to evaluate different programs.
The Stanford Arthritis Self-Management Program (ASMP), most commonly delivered by trained lay leaders, is a generic program widely used for people with rheumatological disorders. We have developed a more specific program expressly for people with osteoarthritis of the knee (OAKP). It includes information designed to be delivered by health professionals and results in improvements in pain, function and quality of life.
Aim: To determine whether, for people with osteoarthritis (OA) of the knee, the OAKP implemented in a primary health care setting can achieve and maintain clinically meaningful improvements in more participants than ASMP delivered in the same environment.

Methods/Design: The effectiveness of the programs will be compared in a single-blind randomized study.
Participants: 146 participants with established OA knee will be recruited. Volunteers with coexistent inflammatory joint disease or serious co-morbidities will be excluded.
Interventions: Participants will be randomised into either OAKP or ASMP groups and followed for 6 months.
Measurements: Assessments will be immediately before and after the intervention and at 6 months. Primary outcome measures will be WOMAC and SF-36 questionnaires and a VAS for pain. Secondary outcomes will include balance, tested using a timed single leg balance test and a timed step test and self-efficacy. Data will be analysed using repeated measures ANOVA.

Discussion: With an aging population the health care costs for people with arthritis are ever increasing. Although cost analysis is beyond the scope of this study, it is reasonable to expect that costs will be greater when health professionals deliver self-management programs as opposed to lay leaders. Consequently it is critical to examine the relative effectiveness of the primary care management strategies available for OA.

Trial Registration: This study is registered with the Australian New Zealand Clinical Trials Registry: 12607000031460

Background

Chronic disease is a major concern with an ageing population, and arthritis is one of the most prevalent chronic diseases affecting 16.7% of the population in Australia [1]. Osteoarthritis is the most common form of arthritis affecting 25% of the population over the age of 65 years. The joint most frequently affected is the knee [2].

Self-management interventions are becoming increasingly popular for many chronic diseases, however the length of program and mode of delivery varies greatly between programs and between illnesses [3]. The programs may utilise a combination of health professionals (physiotherapists, occupational therapists, nurses and dieticians), trained health educators, mental health workers, and occasionally physicians, for program delivery. Other programs have lay leaders who usually deliver a scripted program. The mode of delivery also varies greatly from face to face to audiotape; group or individual contact and more recently internet based programs [4].

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Comparing different self-management models is difficult as the needs of people with chronic diseases differ according to their illness. Asthma and diabetes self-management programs emphasise medication delivery and compliance, whereas self-management for other conditions may focus more on pain management strategies. Even within the broad category of arthritis, the self-management needs of people with different types of arthritis such as rheumatoid arthritis or osteoarthritis are not the same.

One widely utilised arthritis self-management program is the Stanford University's Arthritis Self Management Progam (ASMP), which is delivered by trained lay leaders [5]. The ASMP has been tested widely. The majority of studies have been conducted in the USA or UK. Many, but not all of these studies report program efficacy. Systematic reviews of self-management interventions that include the ASMP have shown there is a trend towards a small benefit for people with arthritis, but the results were not statistically significant and there was a suggestion of publication bias [3,6,7]. At this stage, it is not possible to unequivically claim that ASMP is effective.

In view of the high prevalence of osteoarthritis of the knee and the absence of unequivocal evidence of effectiveness of ASMP, we developed an education self-management program specifically for people with osteoarthritis of the knee (OAKP). The program is delivered by health professionals with information and instruction that utilises their knowledge and skills within a self-management construct. The OAKP has been tested in a quality assurance project [8] and a randomised controlled trial (RCT) the results of which show improvements in quality of life, pain and function compared to a control group [9].

With an aging population the costs associated with arthritis are ever increasing [1]. Although cost analysis is beyond the scope of this study, it is reasonable to expect that costs will be greater when health professionals deliver self-management programs as opposed to lay leaders. Therefore it is important to establish whether delivery by health professionals results in added benefits and/or improvements in outcomes. At present both ASMP and OAKP are offered as clinical services at Arthritis WA.

Accordingly, we propose to conduct a RCT to examine the differences between OAKP, directed and delivered by health professionals, and ASMP, delivered by trained lay leaders.

Aims

To compare the effectiveness of the OAKP and ASMP for people with OA knee.

Hypothesis

A greater proportion of people with osteoarthritis of the knee that complete the OAKP will report clinically meaningful improvements in pain, knee function and quality of life, at 8 weeks, and 6 months compared to those who complete the ASMP.

Methods/Design

Study Design

A two-group single blind, randomised, repeated measure study design will be used to compare the programs (Figure 1). Participants in both groups will continue to receive standard medical management as required.

Group allocation

To ensure manageable numbers for intervention groups, participants will be randomised in blocks. Pre-prepared cards indicating group assignment will be placed in sealed opaque envelopes and drawn as a lottery by a third party for allocation to treatment groups. Allocation will not take place until a whole block has been recruited in order to ensure optimum group sizes. This method of randomisation worked successfully for a previous OAKP RCT [10].

Subjects

As this study will evaluate a clinical service currently provided by Arthritis WA, the study recruitment strategies and selection criteria have been selected to operate within that context. The participants will be men and women with established OA of one or both knees. The operational definition for OA knee used for the OAKP is OA of the knee diagnosed either by clinical examination or by radiological (X-Ray) evidence. The participant will be required to have a referral and a definitive diagnosis of OA made by a family physician/general medical practitioner or specialist physician in order to be eligible to participate in the study. In addition, the American Rheumatology Association clinical classification algorithm will be applied. The overall sensitivity and specificity of this method are 89% and 88% respectively [11]. The inclusion criteria for determining suitability have previously been used for a quality assurance study and a randomised RCT [8,10] and in both it was found to work well. Participants will not be excluded on the basis of severity of symptoms. They will be required to be ≥ 18 years of age, English speaking and to provide consent to randomisation as demonstrated by signed written authority. Participants with rheumatoid arthritis or other inflammatory joint disease, serious co-morbidities, those who plan to have knee surgery within 6 months of commencing the study or who have physical

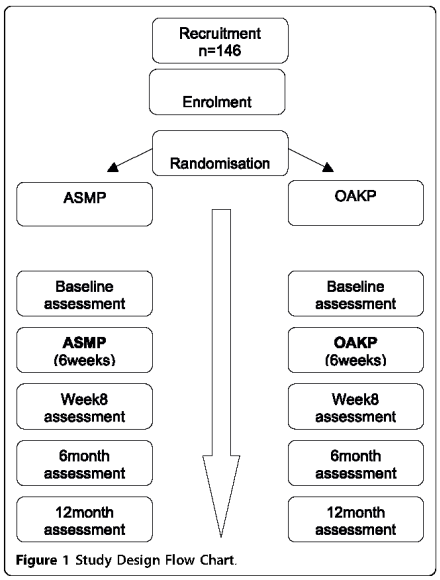

Figure 1 Study Design Flow Chart.

impairments that preclude fulfilment of the requirements of either program will be excluded (Additional file 1).

Recruitment strategies will include active promotion to general practitioners, rheumatologists and health professionals through professional societies. The study will also be offered to those people with osteoarthritis of the knee who make general inquiries to Arthritis WA, and to the general public through advertising and media coverage.

Interventions

Both programs will be delivered over a six-week period with participants attending one session of two and a half hours per week. To facilitate optimum group dynamics, the target size for each group will be 12 participants, although this may vary as a result of recruitment and randomisation.

There will be a pool of 4 group leaders for each program, health professionals for OAKP and lay leaders for ASMP. The health professionals will be trained in delivery of self-management programs and the lay leaders will be experienced ASMP facilitators who have completed the "Train the Trainer course" conducted at Arthritis WA, under licence from Stanford University. Facilitators will work in pairs when delivering the programs.

The fidelity of OAKP and ASMP will be maintained as both programs have manuals for course delivery.

OAKP The health professionals delivering the OAKP will be required to have the knowledge and skills to present information on disease specific topics, exercise advice, and to accurately respond to complex questions.

The Program includes the following aspects of care:

- Osteoarthritis - explanation and implications
- Pain management strategies (cognitive and pharmacological)
- Fitness and exercise (strength, flexibility, aerobic and balance)
- Joint protection
- Nutrition and weight control
- Medication (type, interactions, current trends)
- Correct use of analgesia (use of, therapeutic dosing, types of analgesia, side effects)
- Balance, proprioception and falls prevention,
- Coping with negative emotions
- Self-management skills (SMART goals [**S**pecific, **M**easurable, **A**chievable, **R**ealistic, **T**ime-framed], problem solving, modelling, positive thinking, improving self-efficacy).

ASMP As the ASMP was designed to be delivered by lay leaders to people with a variety of musculoskeletal conditions such as rheumatoid arthritis, osteoarthritis, fibromyalgia and systemic lupus erythematosus, the course content is more generic.

Subjects covered in ASMP include [12]:

- Techniques to deal with problems such as pain, fatigue, frustration and isolation,
- Appropriate exercise for maintaining and improving strength, flexibility, and endurance,
- Appropriate use of medications,
- Communicating effectively with family, friends and health professionals,
- Healthy eating,
- Making informed treatment decisions,
- Disease related problem solving
- Getting a good night's sleep.

Ethical Issues

This study has been approved by the Human Research Ethics Committee at Curtin University of Technology and meets with CONSORT guidelines. It is registered with the Australian New Zealand Clinical Trials Registry, number: 12607000031460.

All participants will provide written informed consent prior to randomisation. Data access and storage will be in keeping with National Health and Medical Research Council guidelines. License agreements have been obtained for SF-36 and WOMAC Questionnaires.

Instruments & Assessments

Baseline Screening/Assessment

Telephone screening will be conducted with people who enquire to enrol into the study. Suitable candidates will have study information sent to them. Following enrolment and written consent, participants will be randomised into groups. At the baseline assessment, demographic information will be collected including: past medical history, current medications including prescribed, over the counter and natural therapies. Records of medical practitioner referral, diagnosis and X-Ray reports will be collected.

Response to Intervention

Participants will be assessed using the following outcome measures at baseline (Week 1), immediately post-intervention (Week 8), and at 6 months after commencing the program. In addition, VAS pain will be assessed on a week-to-week basis during the first 8 weeks- that is the two assessment weeks and the 6 intervention weeks. A research assistant who will remain blind to group allocation will perform all assessments at all time-points. The primary outcomes for the study will be health status, quality of life and pain severity.

Outcome measures

Western Ontario and McMaster Universities (WOMAC) Osteoarthritis index

WOMAC measures health status and assesses pain, stiffness and physical function in patients with OA of the hip or knee. For the purpose of this study the Likert (WOMAC LK3.0) format will be used. The WOMAC questionnaire is self-administered and can be completed in less than 10 minutes. Two major validity studies have shown WOMAC pain, stiffness and physical function subscales are valid and that the questionnaire is reliable and sensitive enough to detect changes in health status following a variety of interventions [13,14].

The Short Form 36 Questionnaire (SF-36)

The SF-36 measures quality of life and has 8 sub-components reflecting both physical and mental status. It is comprised of 36 questions, is self-administered and can be completed in approximately 15 minutes. All estimates of score reliability, from 14 separate studies, for each of the 8 sub-categories of the SF-36 exceed accepted standards for measures used in group comparisons [15]. The SF-36 has been extensively validated in many English speaking countries of the world including Australia [16]. The rationale for using both WOMAC and the SF-36 for this study is that a combined approach using both generic and knee specific measures is considered likely to prove best for knee related problems [17].

Visual Analog Scale (VAS)

VAS will be used to measure participants' pain severity. The VAS is a single dimension horizontal scale, which consists of a 10 cm line on which participants rate their pain from 0-10. Participants are required to place a vertical pen line through the scale at the level of their pain- 0 reflecting No Pain and 10 reflecting the Worst Pain imaginable. The VAS is well established in clinical practice for measuring pain post -surgery, following drug therapy and in response to other interventions in arthritis populations [18].

Modified Timed Up and Go Test

This test is a modification of the "Timed Up and Go" test (mTUG), used to assess basic functional mobility in the elderly [19]. TUG is a widely used clinical outcome tool in which the time taken to stand from sitting, walk 3 m, turn around, return to the chair and sit down is measured. This test is reliable and valid [19]. In this study, the time taken to ascend and descend a 15 cm step has been added to the outward walk, and the length of the walk has been extended to 4 m.

Step Test

This is a test of dynamic standing balance. It involves stepping one foot on, then off a block as quickly as possible in a set time period of 30 seconds. It has high test-retest reliability (ICC > 0.90) good concurrent validity and is sensitive to changes in performance over time [20].

Timed Single Leg balance Test

This is a simple test that assesses the difficulty a person has standing on one leg. The score is the total time (in seconds, to a maximum of 30 seconds) standing on one leg. It is thought that this test is a good predictor of falls in the elderly [21] and is reliable and valid (rc = 0.69) [22].

Arthritis Self-Efficacy Questionnaire

This is an 8-item scale. Participants are asked to complete the questionnaire by circling the number that best reflects the degree to which they are confident they can complete a described task at the present time. The score is the total of the 8 items. This questionnaire has been widely used in arthritis research and has internal consistency and reliability of 0.94 [23].

Statistical Power

Power calculations are based on the achievement of a minimal clinically meaningful improvement [24]. With an alpha (1-tailed) of 0.05 and a sample size of 73 people in each group, this study will have power of 80% to show that the response rate for ASMP is at least as high as the response rate for OAKP. This assumes that the response rates for the ASMP and OAKP groups are equal (at 38.0%, the level of response achieved for the WOMAC function scale in our earlier RCT [10]), and

that a difference of 20.0 points or less is unimportant and allows for 20% drop out.

Data Analysis

Data will be analysed in a blinded manner using SPSS v17 for Macintosh. Treatment groups will be examined for comparability at baseline using unpaired t-tests or Chi-squared test as appropriate. Main comparisons between treatment groups will be performed using an intention to treat analysis. For all subjects who complete the 6-month measurements, previous values will be carried forward to replace any interim missing values.

The proportion of participants achieving minimal clinically meaningful improvement in the health status, quality of life and pain will be computed for each group at each observation time. The effect of the treatment, in terms of the proportion showing minimal clinically meaningful improvement will be examined using Chi-square test. Separate analysis will be conducted for each of the outcome variables of interest.

Further, participants will be classified as overall responders or non-responders. A favourable response to treatment (responder) will be defined according to scenario D of the OMERACT-OARSI criteria [25]. That is, an improvement of ≥ 50% in pain or function and an absolute change of ≥ 20 points on a 100 point scale, OR an improvement of at least 2 of the following: An improvement of ≥ 20% and an absolute change of ≥ 10 in two of pain, function and global health. The proportion of participants achieving responder criteria will be computed for each group at each observation time. The effect of the treatment, in terms of the proportion of responders will be examined using Chi-square test.

Finally, repeated measures ANOVA will be used to examine the differences between groups over time. Statistical significance will be inferred at a 1-tailed $p < 0.05$. Results will not be adjusted for multiple comparisons as all outcomes of interest have been nominated a priori and such adjustment would likely render all findings of interest non-significant, despite their clinical importance [26]. Separate analysis will be conducted for each of the outcome variables of interest.

Discussion

Meta-analyses of self-management have all concluded that it is difficult to compare models between different chronic conditions, and this is also the case with different types of arthritis [3,7,27]. Many disease states exist under the banner of arthritis, and all of them have different symptoms and requirements. People with any type of arthritis can enrol in ASMP, as it is a generic program. Facilitation by lay leaders and the variety of arthritic conditions that can be accommodated in group sessions have advantages in terms of cost and feasibility, for example in small communities.

In contrast, the OAKP is a disease specific education self-management program that was designed for facilitation by health professionals to enable more detailed information specific to OA knee to be included.

The study described in this paper will determine comparative efficacy of these programs and the results will assist in planning future arthritis self-management strategies. The widely used valid and reliable outcome measures along with design features such as randomisation and blinding will minimise bias and facilitate comparison with other studies.

Additional file 1: Eligibility Criteria

Abbreviations

ASMP: Arthritis Self-Management Program; OAKP: Osteoarthritis of the Knee Program; OA: Osteoarthritis; RCT: Randomised controlled trial; WOMAC: Western Ontario and McMaster Universities Osteoarthritis index; SF-36: Short Form 36 Questionnaire; VAS: Visual analog score; mTUG: Modified Timed Up and Go test.

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Authors' contributions

SC and KB were responsible for writing the study protocol and drafting the manuscript. JM, JR, CI, and GC, assisted with study design and provided comments on the drafts and all authors approved the final version of the manuscript.

Competing interests

The authors declare that they have no competing interests.

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Table 1: Eligibility criteria (see page 5 of paper)

Inclusion	Exclusion
Confirmed OA knee	Co-existing inflammatory disease
>18 years of age	Unable to meet study time-points
English speaking	Scheduled knee replacement < 6months
Agrees to randomisation	Serious co-morbidity
Referral from physician	
Able to meet program requirements	

PAPER 4

Study 2 Results Paper

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Self-Management for osteoarthritis of the knee, a randomised controlled trial comparing health professionals and lay leaders.

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ABSTRACT

Objectives

The aim is to compare a disease specific self-management program for people with osteoarthritis (OA) of the knee (the OAK Program), implemented by health professionals with the Stanford University's Arthritis Self-management Program (ASMP) implemented by lay leaders, to determine which whether the OAK Program was more effective that ASMP in terms of function, pain stiffness and quality of life.

Methods

Participants: Medical practitioners referred 180 participants with established OA knee, mean (SD) age of 66.9 (9) years. Volunteers were excluded for coexistent inflammatory joint disease or serious co-morbidities.

Interventions: Participants were randomised into either OAK or ASMP groups. Both groups completed their allocated six-week self-management program following randomisation. Follow-up assessments were completed at eight weeks, six and twelve months.

Measurements: All participants were assessed at baseline, eight weeks, six and twelve months. Primary outcomes measures were WOMAC, SF-36 and VAS pain. Secondary outcomes were self-efficacy; balance using a step test and a timed one-legged balance test; a modified timed get up and go test; global health, and global improvement for achievement in responder and Minimal Clinically Important Improvement (MCII) criteria.

Results

The proportion of responders was greater in the OAK Program group than the ASMP group (46% versus 29% at eight weeks), although significance declined over time.

OAK had significant improvements compared with ASMP in WOMAC Pain, Physical Function and Total score domains. In both groups, participants' response to treatment were demonstrated in SF-36, with OAK demonstrating significant improvements in Physical Function and General Health until 12months. VAS pain improved during the eight week clinic phase in the OAK group, mean (SE) 5.51 (0.25) to 4.57 (0.25) compared with the ASMP group,

5.12 (0.24) to 4.71 (0.25) *p*=0.04. There was no significant difference between groups in the secondary outcomes.

Conclusions

The OAK Program demonstrated more improvements than the ASMP in most outcomes over time although not necessarily at the same level since some became non-significant over time. The improvements in pain and function have implications for improved mortality and decreased disability for people with OA of the knee.

This study is registered with the Australian New Zealand Clinical Trials Registry: 12607000031460

Background

As the population ages chronic diseases are a major concern in Australia. Arthritis accounts for greater health expenditure than coronary heart disease, depression, asthma, stroke and diabetes (Brooks and Hart 2000). Osteoarthritis (OA) is the most common form of arthritis and occurs in the knees, neck, lower back, hip and fingers. The most commonly affected joint is the knee and it has a substantial influence on quality of life and imposes a heavy economic burden on the community (Access Economics 2007).

SM is increasingly being utilised in the treatment of chronic diseases because it aims to enable the patient to gain the skills and motivation needed to manage their chronic illness. Asthma, hypertension, diabetes, and arthritis are among those chronic diseases that use SM as a treatment option. There are many different styles and models vary depending on the illness. Some use health professionals to lead the groups while others use lay leaders. Delivery of the program can be face-to-face, in groups, via the Internet, or by telephone or mail. Systematic reviews have suggested that SM has less effect on arthritis than other health conditions such as asthma, diabetes and hypertension because pain and function are more complex components of SM than medication compliance (Warsi, LaValley et al. 2003; Chodosh, Morton et al. 2005).

SM differs from most medical interventions in that the core premise is to improve the patient's confidence in managing the chronic illness by strengthening self-efficacy. It is argued that this allows the use of lay leaders to deliver general information related to the chronic illness, rather than specific skills or information. Certainly, for arthritis SM, lay leaders are used more than health professionals, however for other chronic diseases such as asthma and diabetes that are medication orientated, the facilitators are usually health professionals.

The industry standard for arthritis SM is the Stanford University Arthritis Self-Management Program (ASMP). The central tenet of the ASMP is based on

self-efficacy theory (Lorig and Holman 2003) and it is facilitated by lay leaders who deliver a scripted, generic program.

Meta-analyses have shown that there is little robust evidence to support the claims of benefit following use of the ASMP, with little evidence of improvements if any, seen in pain and function (Warsi, Wang et al. 2004; Chodosh, Morton et al. 2005). Furthermore, there is some suggestion of publication bias (Warsi, LaValley et al. 2003; Chodosh, Morton et al. 2005). As well as limited evidence to support the value of SM in arthritis, recent recommendations suggest that the skills and expertise of health professionals should be incorporated in SM programs (Jordan and Osborne 2006; Jordan and Osborne 2007; Taylor and Bury 2007).

A SM education program designed for people with OA of the knee (the OAK Program) delivered by health professionals, has previously demonstrated improvements in pain, function and quality of life, in a quality assurance study and a randomised controlled trial (Coleman, Conroy et al. 2002; Coleman, Briffa et al. 2008a). The OAK Program is condition specific, with the content tailored to meet the needs of people with OA of the knee and is designed to utilise the skills and expertise of health professionals within a SM format.

To test the OAK Program further, we designed a randomised controlled trial (RCT) comparing it with the ASMP. The results of this study are described in this paper.

Hypothesis

A greater proportion of people with OA of the knee completing the OAK Program will achieve a minimal clinically important difference in pain, function and quality of life, at eight weeks, six and twelve months compared with those who complete the ASMP.

Methods

Study Design

A two-group randomised, controlled, repeated measures study design compared the disease specific OAK Program delivered by health professionals with the generic ASMP delivered by lay leaders. Throughout the study all participants in both groups continued to receive standard medical management as required. This study adhered to intention to treat principles and complied with CONSORT guidelines. The study design is summarised in Figure 1 and has been described in greater detail elsewhere (Coleman, McQuade et al. 2010).

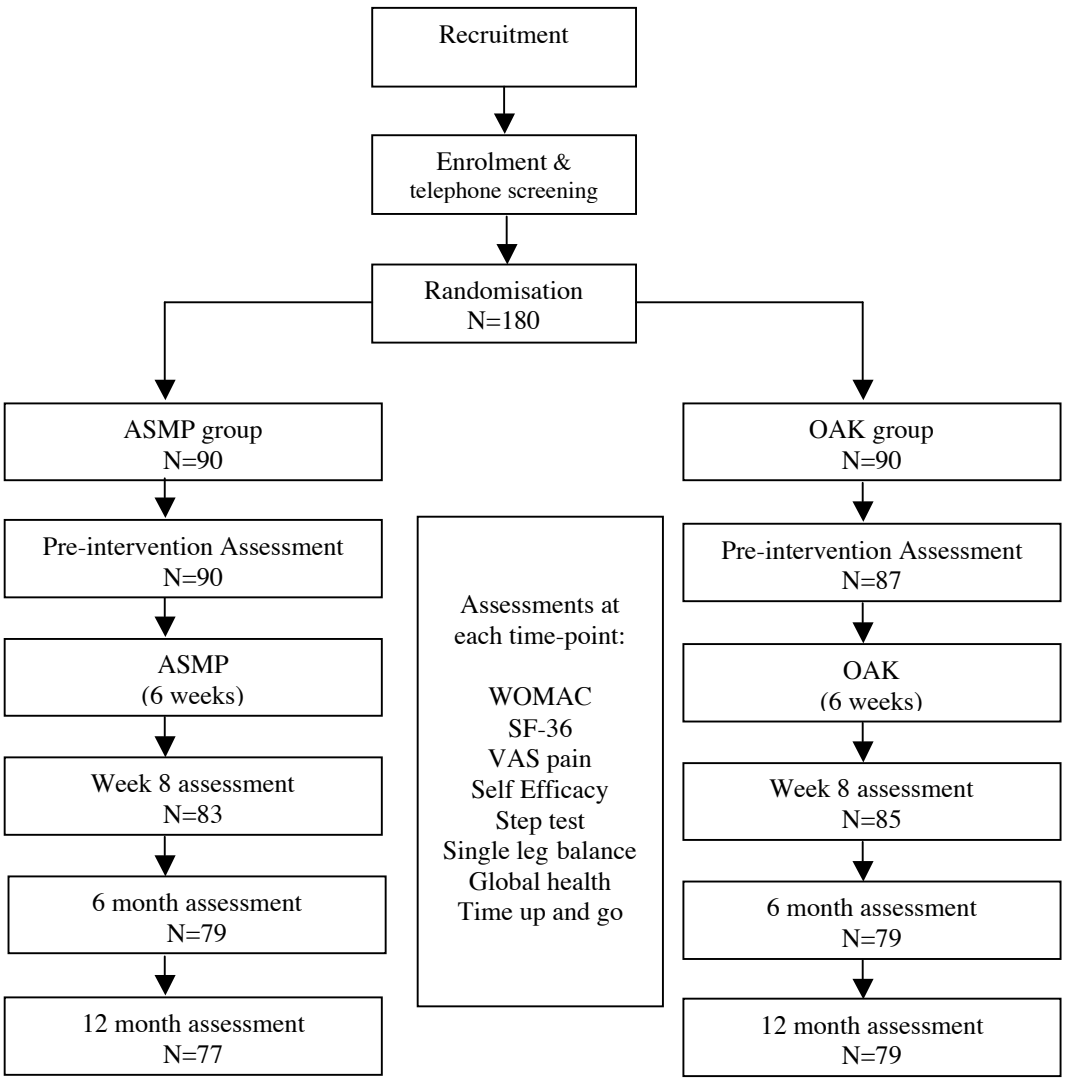

Figure 1: Study Design Flow Chart and evaluation tools used at each assessment. N=number of participants included in the data analyses. This includes values from returned posted questionnaires from non-attendees and last value carried forward for other missing data.

Group allocation: Participants were randomised in blocks. Pre-prepared cards indicating group assignment were placed in sealed opaque envelopes and drawn as a lottery by a third party for allocation to treatment groups (ratio 1:1). Allocation did not take place until a whole block was recruited in order to ensure optimum group sizes. This method of randomisation had been shown to be successful in a previous OAK RCT (Coleman, Conroy et al. 2002).

Both programs had four facilitators. Health professionals delivering the OAK Program had been trained in the delivery of SM programs. The four lay leaders delivering the ASMP were skilled ASMP facilitators having completed the "Train the Trainer" course conducted at Arthritis Western Australia, under licence from Stanford University. Both the OAK Program and ASMP have manuals for program delivery to ensure that fidelity is maintained.

Facilitators delivering either the OAK program or the ASMP were unavoidably aware of which program participants attended however participants were unaware which program they were allocated to, and assessors and data analysts were blinded to group allocation.

Sample

Convenience sampling was used for recruitment of the study participants. People who enquired about arthritis SM at Arthritis Western Australia were invited to enrol in the study as with previous OAK Program studies. It was also offered to the general public through advertising and media coverage. Further recruitment strategies included active promotion to general practitioners, rheumatologists and health professionals through professional societies.

Interventions –

The OAK Program

The Program involves many aspects of care:

- OA – explanation and implications
- Pain management strategies (cognitive and pharmacological)
- Fitness and exercise (strength, flexibility, aerobic and balance)

- Joint protection
- Nutrition and weight control
- Medication (type, interactions, current trends)
- Correct use of analgesia (therapeutic dosing, types of analgesia, side effects)
- Balance/falls prevention, proprioception
- Coping with negative emotions
- Self-management skills (specific, measurable, achievable realistic time-framed goals; problem solving; modelling; positive thinking; improving self-efficacy).

ASMP

The ASMP content is general rather than specific as the central tenet is that improved self-efficacy rather than the acquisition of skills and knowledge improves health outcomes (Marks and Allegrante 2005; Taylor and Bury 2007) and the use of lay leaders is more effective in this process than health professionals.

Subjects covered in the ASMP include: (Stanford Patient Education Center)

- Techniques to deal with problems such as pain, fatigue, frustration and isolation,
- Appropriate exercise for maintaining and improving strength, flexibility, and endurance,
- Appropriate use of medications,
- Communicating effectively with family, friends, and health professionals,
- Healthy eating,
- Making informed treatment decisions,
- Disease related problem solving
- Getting a good night's sleep.

To facilitate optimum group dynamics, the target group size for each group was set at twelve participants.

Subjects

Participants: 180 people 59 male and 121 female of mean (SD) age 66.9 (9) years referred by medical practitioners with previously diagnosed OA of the knee were enrolled into the study. The operational definition for OA knee was diagnosis by a medical practitioner, based on clinical examination and/or medical imaging. Participants were not excluded on the basis of severity of symptoms. The inclusion criteria for determining suitability have successfully been employed for a previous Quality Assurance study and a RCT (Coleman, Briffa et al. 2008a; Coleman, Briffa et al. 2008b). Inclusion and exclusion criteria are indicated in Table 1.

Inclusion	Exclusion
Confirmed OA knee	Co-existing inflammatory disease
>18 years of age	Unable to meet study requirements
English speaking	Scheduled knee replacement <6months
Agrees to randomisation	Serious co-morbidity
Referral from physician	
Able to meet program requirements	

Table 1: Eligibility criteria

Ethical Issues

This study was approved by the Human Research Ethics Committee at Curtin University of Technology (HR12) and registered with the Australian and New Zealand Clinical Trial Registry, number: 12607000031460.

All participants provided written informed consent prior to randomisation. Data access and storage was in keeping with National Health and Medical Research Council guidelines (National Health and Medical Research Council 2007). License agreements were obtained for the SF-36 and WOMAC Questionnaires.

A number of amendments to the trial protocol were implemented between the initial registration and commencement of the study. The number of participants recruited was increased from 146 to 180, as the rate of dropouts in the RCT underway at the time was greater than anticipated. Furthermore, the follow-up component of the study was extended to twelve months as it was considered that important information on long-term effects would be obtained by this extension. In addition, self-reported global health and global improvement measures were added, as this was necessary to meet OMERACT/OARSI responder criteria.

A modified timed up and go test was also included as there is evidence to suggest that using a functional measure as well as a self-reported measure is preferable in order to obtain the most comprehensive assessment of functional limitations (Maly, Costigan et al. 2006) as self- reported functional outcome measures tend to be influenced by pain (Boonstra, De Waal Malefijt et al. 2008)

Response to Intervention

Participants were assessed using the outcome measures listed in Figure 1 at each of the time points shown. In addition, VAS pain was assessed on a week-to-week basis during the first eight weeks including the six intervention weeks.

The proportion of participants achieving MCII in health status, quality of life, pain, global health and TUG were computed for each group at each observation time. MCII data are not available for all variables as there are not published values for all variables measured in this study.

MCIIs were defined as: (Bellamy, Bell et al. 2005; Tubach, Ravaud et al. 2005)

Health status using WOMAC Physical Function (0 to 100),

- Absolute change of –9.1

Pain (0 to 100mm VAS)

- absolute change of –19.9

Quality of life using SF-36

- absolute change of +5 points

Global health

- absolute change of 18.3

Participants were further classified as overall responders or non-responders. A favourable response to treatment (responder) was defined according to the guidelines of the Outcome Measures in Rheumatology Clinical Trials and Osteoarthritis Research Society International (OMERACT-OARSI) (Pham, van der Heijde et al. 2004). That is, an improvement of ≥50% in pain or function and an absolute change of ≥20 points on a 100 point scale, OR an improvement of at least two of the following: An improvement of ≥20% and an absolute change of ≥10 in two of pain, function and global health. The proportion of participants achieving MCII and responder criteria was computed for each group at each observation time.

Statistical Power

A priori power calculations were based on the achievement of a minimal clinically important improvement (Tubach, Ravaud et al. 2005). This study was designed to have a power of 80% to show that the response rate for the ASMP was at least as high as the response rate for the OAK Program. This assumes that the response rates for the ASMP and OAK groups are equal (at 38.0%, the level of response achieved for the WOMAC function scale in our earlier RCT (Coleman, Conroy et al. 2002)), and that a difference of 20.0 points or less is unimportant, with a sample size of 180 and allowing for 20% drop out, and an alpha (1 tailed) of 0.05.

Single tail design was chosen since the QA study and the RCT comparing OAK and a control group both showed that the OAK program resulted in improvements in pain, function and quality of life; it was expected that the same results would be apparent in this RCT. Similar claims have been published on ASMP, and it was likely that both groups would improve with the primarily objectives looking at the difference in improvements between groups. We did not expect either group to decline during the RCT and

therefore chose single tailed study design.

Data Analysis

Data were analysed in a blinded manner using SPSS v17 for Macintosh. Comparisons between treatment groups were performed using an intention to treat analysis. All participants were encouraged to attend all follow-up measurements regardless of the level of attendance at the group sessions. Where data were missing the previous value was carried forward. The proportion of participants achieving responder criteria and MCII was computed for each group at each observation time and Chi-square tests were used to compare proportions between groups.

Further, between group differences in changes over time (baseline, eight-weeks, six and twelve months) were examined using repeated measures ANOVA.

A separate analysis was conducted for each outcome variable. Statistical significance was inferred at a 1-tailed $p<0.05$. Results were not adjusted for multiple comparisons as all outcomes of interest were nominated a priori and such adjustment would likely render all findings of interest non-significant despite their clinical importance (Perneger 1998).

Results

Although every effort was made to assess participants in both groups at all time-points, some participants, especially in the ASMP group refused to comply even with postal assessments. There was discernible discontent to requests for follow-up assessment with some participants refusing any communication with study co-ordinators. Anecdotally, the common thread of complaint was that the ASMP resembled a “support group” rather than a specific OA program, and some of those participants that were drop-outs were dissatisfied enough to refuse to commit to follow-up assessments or to complete posted questionnaires. Another anecdotal comment from the ASMP group participants was that they expected exercise instruction and specific information on OA of the knee and neither was forthcoming. Several

participants who were employed but had arranged time off from work to attend the ASMP were disgruntled about their “waste of time” and refused any further participation. In some of the ASMP group participants there was palpable anger associated with this sentiment. One ASMP participant wrote a formal letter of complaint to Arthritis Western Australia.

Groups were comparable at baseline (Table 2).

Table 2:

Baseline characteristics of participants enrolled in the OAK Program and the ASMP

Patient Characteristics	**OAK** n=90	**ASMP** n=90
Male:Female	30:60	29:61
Age (years) Mean (SD)	67.6 (8.23)	66.3 (9.84)
Socio-Economic Index* by Post Code	Number (%)	
Top 25%	53 (58.8)	56 (66.2)
50-75%	11 (12.2)	13 (14.4)
25-50%	10 (11.1)	9 (10)
10-25%	10 (11.1)	8 (8.9)
Bottom 10%	6 (6.6)	4 (4.4)
*Index measured in quintile ranges		
Co-morbidities	**Number**	
Total	223	203
Mean (SD)	2.47 (1.9)	2.25 (1.73)
Cardiovascular	73	71
Mental Health	13	15
Gastrointestinal	23	19
Musculoskeletal (other than knee)	59	49
Endocrine	15	13
Osteoporosis	11	12
Other	29	24
None	13	15
Baseline values; mean (SD)		
VAS pain (0 to 10)	5.52 (2.17)	5.12 (1.74)
WOMAC Pain (0 to 10)	3.67 (1.58)	3.65 (2.47)
WOMAC Physical Function (0 to 10)	3.66 (1.83)	3.57 (1.68)
SF-36 PCS (0 to 100)	34.17 (9.05)	35.47 (8.85)
SF-36 MCS (0 to 100)	50.44 (10.78)	50.63 (10.73)
Global Health (0 to 10)	6.40 (2.29)	6.32 (2.34)

MCIIs

The proportion of participants achieving MCIIs in WOMAC Physical Function between baseline and post-intervention was greater for the OAK Program participants than for the ASMP (Table 3). At later follow-ups the proportion of people maintaining the MCII compared with baseline remained greater in the OAK Program group but the difference between groups was no longer significant.

Post-intervention more participants from the OAK Program group achieved MCIIs than from the ASMP group in all SF-36 domains apart from SF-36 Mental Health (Table 3), albeit with difference not significant for some variables. The number of participants achieving MCII in SF-36 Physical Function was substantial in both groups and well maintained throughout follow-up. However, the proportion from the OAK Program group was significantly greater immediately post-intervention and at six months, and approached significance at 12 months (Table 3).

Similar results were seen in General Health with more people from the OAK Program group achieving more MCIIs than ASMP at all time points –with differences approaching significance ($p=0.07$) immediately post-intervention and significant at six and twelve months (Table 3).

Responders

The number of the OAK group responders was greater than the ASMP group responders at all time-points (Table 3), however this difference was only significant at the post-intervention time-point. Post-intervention almost half the OAK group were classified as responders compared with less than one third of the ASMP group.

Table 3: Minimal Clinically Important Improvements and participant responders using OMERACT-OARSI criteria (Tubach, Ravaud et al. 2005) pre-intervention (baseline), post-intervention (week eight), six-months and twelve-months

	% (Number with MCII)		
Pre-intervention to 8 weeks	OAK	ASMP	*P* value
WOMAC PF	36% (31)	23% (21)	0.04
SF-36 Physical Function	70% (60)	42% (38)	<0.001
SF-36 Role Physical	41% (36)	32% (29)	0.13
SF-36 Pain	48% (42)	44% (40)	0.36
SF-36 General Health	47% (41)	35% (32)	0.07
SF-36 Social Function	42% (37)	40% (36)	0.42
SF-36 Vitality	53% (46)	44% (40)	0.16
SF-36 Role Emotional	32% (28)	26% (24)	0.26
SF-36 Mental Health	29% (25)	39% (35)	0.10
VAS Pain	39% (34)	32% (28)	0.20
Global Health	25% (22)	22% (20)	0.36
Responder	46% (40)	29% (26)	0.01
Pre-intervention to 6 months			
WOMAC PF	35% (30)	30% (27)	0.30
SF-36 Physical Function	65% (57)	51% (46)	0.04
SF-36 Role Physical	33% (29)	36% (33)	0.38
SF-36 Pain	45% (39)	50% (45)	0.30
SF-36 General Health	52% (45)	33% (30)	0.01
SF-36 Social Function	42% (37)	36% (33)	0.26
SF-36 Vitality	54% (47)	49% (44)	0.29
SF-36 Role Emotional	23% (20)	33% (30)	0.08
SF-36 Mental Health	30% (26)	29% (26)	0.50
VAS Pain	36% (31)	31% (27)	0.30
Global Health absolute	25% (22)	25% (23)	0.57
Responder	41% (36)	33% (30)	0.17
Pre-intervention to 12 months			
WOMAC PF	36% (31)	29% (26)	0.20
SF-36 Physical Function	62% (54)	50% (45)	0.07
SF-36 Role Physical	45% (39)	41% (37)	0.36
SF-36 Pain	54% (47)	55% (50)	0.48
SF-36 General Health	56% (49)	36% (33)	0.007
SF-36 Social Function	35% (31)	37% (34)	0.44
SF-36 Vitality	50% (44)	53% (48)	0.41

SF-36 Role Emotional	31% (27)	36% (33)	0.26
SF-36 Mental Health	38% (33)	39% (35)	0.50
VAS Pain	42% (37)	37% (33)	0.30
Global Health	30% (24)	20% (18)	0.15
Responder	43% (39)	37% (34)	0.21

Changes over time

Overall, participants had significant improvements (*time* $p<0.02$) in all of the WOMAC domains (Table 4). The magnitude of improvement was greater in the OAK Program group in all domains with significant differences in the Physical Function and Total domains (*group x time* $p = 0.04$ and approaching significance in the Pain domain (*group x time* $p=0.08$).

Similarly, there were improvements over both groups in all SF36 domains except GH (*time* $p\leq0.05$). The magnitude of improvement in the OAK Program group was significantly greater than the ASMP group in Physical Function (*group x time* $p\leq0.002$) (Table 4). General Health decreased in the ASMP group but increased in the OAK Program group (-1.5 versus +4.7 respectively; *group x time* $p=0.009$)

There were also significant improvements in VAS Pain scores (Figure 2), SE, TUG, and step tests (*time* $p<0.001$) but the magnitude of the change did not differ significantly between groups in any of the variables (*group x time* $p\geq0.09$) (Table 4).

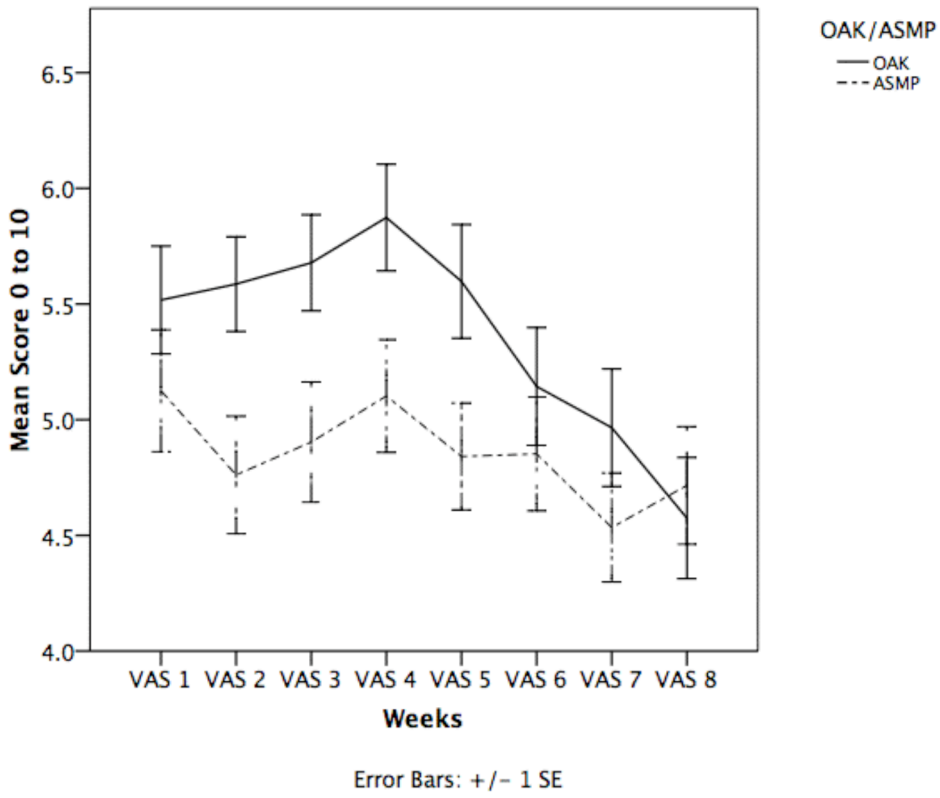

Figure 2: VAS pain mean (SE) OAK and ASMP pre-intervention (baseline), weekly until post-intervention (week eight); group x time differences, *p*=0.02

Table 4: Results for WOMAC, SF-36, mTUG, Step Test, Single Leg Balance, Global Health and Self-Efficacy: pre-intervention (baseline), post-intervention (week eight), six-months and twelve-months using repeated measures ANOVA; Data are estimated marginal mean (SE) with the mean (single sided 95% CI) difference of change between the groups at each time-point. Single sided lower confidence limit indicating that the 95% CI is greater than the value shown. All p-values are single tailed.

WOMAC	OAK Mean (SE)	ASMP Mean (SE)	Difference in change between group means	Single sided 95% CI of the mean difference	p-value for difference in change between groups	*p*-value for ANOVA Group x time interaction
Pain (0 to 20)						
Pre intervention	7.34 (0.36)	7.31 (0.35)				
Post intervention	6.16 (0.35)	6.76 (0.34)	0.64	0.00	0.05	
6 Months	5.84 (0.39)	6.26 (0.38)	0.45	-0.35	0.17	
12 Months	5.26 (0.37)	6.17 (0.36)	0.94	0.13	0.02	0.08
Stiffness (0 to 8)						
Pre intervention	3.57 (0.21)	3.54 (0.22)				
Post intervention	3.20 (0.19)	3.21 (0.20)	-0.02	-0.42	0.45	
6 Months	3.25 (0.18)	3.06 (0.19)	0.16	-0.26	0.21	
12 Months	2.88 (0.18)	3.12 (0.19)	-0.26	-0.72	0.17	0.17
Physical Function (0 to 68)						
Pre intervention	24.94 (1.29)	24.31 (1.26)				
Post intervention	20.37 (1.28)	21.55 (1.25)	0.26	-0.52	0.05	
6 Months	21.15 (1.43)	20.86 (1.40)	0.50	-0.22	0.40	
12 Months	18.73 (1.39)	21.05 (1.36)	0.43	0.06	0.02	0.04
Total (0 to 96)						
Pre intervention	35.86 (1.71)	35.05 (1.68)				
Post intervention	29.75 (1.69)	31.53 (1.65)	2.58	0.04	0.04	
6 Months	30.27 (1.88)	30.20 (1.84)	0.73	-2.51	0.35	
12 Months	27.16 (1.85)	30.35 (1.81)	4.00	0.55	0.02	0.05

SF-36 (0 to 100)						
Physical Function						
Pre- intervention	46.43 (2.41)	50.77 (2.37)				
Post-intervention	56.89 (2.30)	54.44 (2.26)	7.79	3.77	0.001	
6 Months	58.50 (2.37)	55.77 (2.33)	7.07	2.80	0.003	
12 Months	57.98 (2.57)	55.61 (2.53)	6.71	1.74	0.01	0.002
Role Physical						
Pre- intervention	30.74 (4.17)	32.22 (4.10)				
Post-intervention	49.13 (4.38)	41.94 (4.31)	8.66	-1.07	0.07	
6 Months	43.10 (4.53)	43.88 (4.45)	0.69	-9.51	0.45	
12 Months	47.59 (4.52)	48.61 (4.52)	0.46	-10.74	0.47	0.23
Body Pain						
Pre- intervention	44.13 (2.11)	43.98 (2.08)				
Post-intervention	49.80 (2.01)	49.22 (1.98)	0.43	-4.35	0.48	
6 Months	50.43 (2.17)	49.63 (2.31)	0.65	-4.43	0.41	
12 Months	52.37 (2.27)	51.64 (2.24)	0.58	-4.54	0.42	0.49
General Health						
Pre- intervention	63.16 (1.90)	66.77 (1.86)				
Post-intervention	66.93 (1.98)	66.14 (1.95)	4.40	1.21	0.02	
6 Months	67.56 (1.90)	65.94 (1.87)	5.23	1.69	0.007	
12 Months	67.90 (1.92)	65.26 (1.89)	6.25	2.43	0.003	0.009
Vitality						
Pre- intervention	51.95 (2.17)	51.77 (2.13)				
Post-intervention	57.29 (1.92)	55.44 (1.89)	1.67	-2.41	0.24	
6 Months	56.55 (2.02)	55.50 (1.99)	0.87	-3.85	0.37	
12 Months	57.06 (1.99)	56.77 (1.96)	0.11	-4.79	0.48	0.45
Social Function						
Pre- intervention	67.38 (2.64)	71.94 (2.59)				
Post-intervention	75.14 (2.43)	75.27 (2.39)	4.43	-1.76	0.16	
6 Months	74.28 (2.54)	74.72 (2.49)	4.12	-1.86	0.12	
12 Months	71.21	76.11	-0.34	-6.81	0.46	0.45

	(2.75)	(2.70)				
Role Emotional						
	60.15	62.22				
Pre- intervention	(4.44)	(4.36)				
Post-	68.58	71.11				
intervention	(4.28)	(4.20)	-0.46	-10.10	0.46	
	60.15	71.85				
6 Months	(4.46)	(4.39)	-9.63	-20.79	0.07	
	64.67	75.55				
12 Months	(4.20)	(4.13)	-8.81	-20.48	0.10	0.12
Mental Health						
	72.13	71.77				
Pre- intervention	(1.63)	(1.61)				
Post-	73.37	73.46				
intervention	(1.69)	(1.67)	-0.45	-3.88	0.41	
	73.47	74.22				
6 Months	(1.73)	(1.70)	-1.11	-4.51	0.29	
	74.48	75.46				
12 Months	(1.60)	(1.57)	-1.34	-4.89	0.26	0.45
mTUG (seconds)						
	12.32	13.47				
Pre intervention	(0.45)	(0.44)				
	11.52	12.63				
Post-intervention	(0.44)	(0.44)	-0.03	0.68	0.46	
	11.71	12.35				
6 Months	(0.52)	(0.52)	0.50	1.35	0.16	
	11.12	12.23				
12 Months	(0.48)	(0.47)	-0.04	0.76	0.46	0.30
Step test R (steps /30 seconds)						
	24.00	23.23				
Pre intervention	(0.76)	(0.75)				
	27.72	26.97				
Post-intervention	(0.76)	(0.75)	-0.02	-1.31	0.46	
	29.47	27.51				
6 Months	(0.81)	(0.81)	1.19	-0.32	0.08	
	30.02	28.40				
12 Months	(0.84)	(0.83)	0.85	-0.64	0.17	0.15
Step test L (steps /30 seconds)						
	23.93	23.06				
Pre intervention	(0.73)	(0.72)				
	28.11	26.80				
Post-intervention	(0.80)	(0.79)	0.44	-0.88	0.26	
	29.82	27.54				
6 Months	(0.80)	(0.80)	1.41	-0.02	0.05	
	30.49	28.11				
12 Months	(0.85)	(0.85)	1.51	-0.01	0.05	0.06
Balance Right (seconds)						
	16.85	16.36				
Pre-intervention	(1.20)	(1.17)				
	19.12	18.73				
Post-intervention	(1.22)	(1.19)	-0.09	-2.28	0.47	
	16.98	17.28				
6 Months	(1.20)	(1.17)	-0.78	-2.88	0.27	
	16.69	16.92				
12 Months	(1.22)	(1.19)	-0.72	-2.97	0.29	0.48

Balance Left (seconds)						
Pre-intervention	16.97 (1.22)	17.03 (1.20)				
Post-intervention	17.94 (1.20)	17.80 (1.18)	0.38	-1.95	0.36	
6 Months	16.09 (1.22)	16.99 (1.19)	-0.65	-2.97	0.31	
12 Months	16.15 (1.22)	15.90 (1.19)	0.48	-1.90	0.36	0.41
Global Health (0 to 10cm)						
Pre-intervention	6.40 (0.25)	6.32 (0.24)				
Post-intervention	6.61 (0.18)	6.18 (0.18)	0.34	0.21	0.18	
6 Months	6.58 (0.20)	6.56 (0.20)	-0.07	-0.72	0.43	
12 Months	6.42 (0.19)	6.32 (0.18)	0.01	-0.62	0.48	0.31
Self- Efficacy (0 to 80)						
Pre-intervention	48.41 (1.66)	47.60 (1.62)				
Post-intervention	55.75 (1.55)	51.92 (1.51)	3.01	-1.13	0.49	
6 Months	54.91 (1.54)	52.50 (1.50)	1.60	-2.64	0.26	
12 Months	54.93 (1.57)	53.13 (1.53)	1.00	-3.27	0.45	0.30

Discussion

In our comparison between two SM programs we found that the number of responders immediately following the intervention was substantially greater in the OAK Program group than the ASMP group, providing solid support for the value of the disease specific OAK Program led by health professions for people with OA of the knee.

Classification as a responder reflects a reduction in pain and an improvement in physical function. Pain relief or improved function is not a common finding in SM programs for people with OA of the knee, therefore this study adds a new dimension to the discussion of SM programs. Furthermore, it is supported by the evidence that the combination of improvements in physical function and pain variables are associated with improved function in people

with OA knee (Fransen and McConnell 2008) and that can be directly related to reduction in disability and mortality (Nuesch, Dieppe et al. 2011).

Pain was assessed using several measures. While WOMAC Pain is disease specific, SF-36 Body Pain is known to reflect pain from other causes, notably co-morbidities and it may be that this measure captured non OA knee pain (Bombardier, Melfi et al. 1995). VAS pain decreased significantly in the OAK group at four weeks and continued to decrease until eight weeks, whereas there was no consistent pattern of improvement in the ASMP group. This same pattern of improvement in the OAK Program participants has been identified in previous studies (Coleman, Briffa et al. 2008a; Coleman, Briffa et al. 2008b).

An important finding of the study is the number of participants from both groups that responded favourably to the self-management intervention with improvements demonstrated in the majority of variables measured. As all participants participated in a group SM intervention the results of this study provides no comparison with a no intervention control. In our earlier study comparing the OAK Program with a usual care control group (Coleman, Conroy et al. 2002) we found the OAK program to result in significantly greater improvement in WOMAC pain, physical function and total scores. The advantage in between-group difference in change was evident at post-treatment and 6-months follow-up in the physical function and total scores, however by 6-months the improvement in pain was comparable between groups. In addition, there were improvements from baseline to 8-weeks in the SF-36 scales Physical Function, Role Physical, Body Pain, Vitality and Social Function in the OAK group compared with the control group. These differences were maintained at 6-months. Although direct comparison with the findings of this study need to be interpreted with caution, the magnitude of the difference of changes and proportion of participants responding to the OAK Program were very similar between the two studies, suggesting that both of the SM interventions implemented in this study would be more effective than usual care.

There is no clear evidence that identifies the mechanisms involved with successful SM and it may be that it is due to the structured nature of the intervention or other non-specific mechanisms such as group dynamics. Nevertheless, in SM programs that are medication-orientated there appears to be consensus that they increase adherence to medications (Chodosh, Morton et al. 2005). Certainly in the OAK Program, pharmacological therapy and pain relief are included in the syllabus. Although pain and medications are included in the syllabus of the ASMP, these areas are covered at a very superficial level in keeping with the knowledge of lay leaders.

The components of the OAK Program that may have contributed to the marked decrease in pain at week four included the emphasis placed on the benefits of exercise and the encouragement provided to progressively increase exercise. The health professional leaders also provided exercise modelling and advice when participants encountered difficulties. In addition, instruction in pharmacological and cognitive pain management and information on therapeutic drug dosing to promote effective pain relief was emphasised. This emphasis appears to be important since it is suggested that a person in chronic pain could be fearful of an activity they expect to aggravate pain and avoidance behaviour due to fear of pain is known to result in decreased daily activity that eventually leads to disability (Vlaeyen and Linton 1999). Whether or not an activity is performed might be influenced by confidence in being able to achieve it despite the pain or how well the individual is able to manage the pain.

Self efficacy is considered the central component of successful SM but there is no evidence that indicates the extent to which SE is an independent variable relating to SM. Nonetheless, most SM trials include SE measures among their primary outcomes. Both the OAK Program group and the ASMP group demonstrated significant within group improvements in SE that was maintained until the 12-month follow-up, however the magnitude was small. Improved SE is consistent with the tenet that SM is based on SE theory (Lorig and Holman 2003) and with the findings of other studies of SM using ASMP that have routinely report improvements in SE (Lorig, Mazonson et al.

1993; Barlow, Turner et al. 1998; Lorig, Gonzalez et al. 1999; Barlow, Turner et al. 2000). Our study demonstrates that improvements in SE in response to the OAK Program are of similar magnitude to those in response to ASMP. However there is no published benchmark upon which to compare the size of improvement in SE. Moreover, it is unclear whether high levels of SE are a consequence rather than a cause of SM (Taylor and Bury 2007).

Enrolment in our study was self-initiated by many of our participants, who then approached their general practitioners for referral. Self-initiated enrollment may produce a potential bias as those people who volunteer may already be predisposed to benefit from SM (Newbould, Taylor et al. 2006; Taylor and Bury 2007) and may not be a true reflection of health patterns in the community. The highest socioeconomic group was over represented in this study with the possibility that our study results may overstate the likely impact on the wider community since there is the potential that people with higher education levels will have better improvements.

Because of the nature of the study design, program facilitators could not be blind. This and the perception of the efficacy of the treatments by the health care providers may have influenced how the patients perceived their pain and resulted in improved pain ratings (Hirsh, Atchison et al. 2005). In addition, self-reporting of pain may be effected by bias, as patients are keen to “do well” and to please health care providers by reporting an improvement when there may not have been one.

Global health did not change at any time-point in either group. This may be partially explained because patients asked to score their health up to twelve months ago, rely on speculation that is influenced by their current state of health. Thus the evaluation of difference between current health status and pre-existing health status is retrospective and may be inaccurate, correlating highly with their present state (Norman, Stratford et al. 1997).

The attrition rate was not foreseen at the beginning of the study and although both groups had non-attendees at follow-up assessments it was especially

problematic in the ASMP group. Every attempt was made to retain the study population. However, attendance dropped off considerably at six months (OAK=15% and ASMP=28%) and dramatically at twelve months (OAK=26% and ASMP=44%). All non-attending participants received posted self-reported questionnaires with postage paid self-addressed envelopes enclosed. Not all participants returned the questionnaires.

Conclusion

This report describes the outcome of the first RCT to compare two different SM programs, one disease specific (the OAK Program and one generic, the ASMP).

Both program groups demonstrated improvements in most outcomes over time, however the OAK group consistently demonstrated more significant improvements when compared with ASMP group in the domains reflecting physical function. Importantly, the OAK Program was not inferior in outcome in any of the important domains. The implications of these findings are of major importance because improvements in pain and function have been linked to reductions in disability and mortality (McCarthy, Mills et al. 2004; Nuesch, Dieppe et al. 2011). Further research is needed to reinforce these findings and investigate other important issues such as cost-effectiveness of the interventions.

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CHAPTER 4

Discussion

Findings from the studies constituting this thesis were positive and provide valuable support for the premise that SM programs are of great benefit in the management of OA. The results also suggest that the incorporation of health professionals as leaders of such programs produces greater benefits than when the programs are led by lay leaders.

The comparison of the OAK Program with a control group (Study 1), demonstrated significant improvements in mean difference of change between the groups in pain, quality of life and function at eight weeks with the improvements maintained at six months follow-up. There were also more responders and participants achieving MCII in the OAK group compared with the control group at both eight weeks and six months. The comparison between the OAK Program and the ASMP (Study 2) identified the fact that while both groups showed improvement, the participants in the OAK Program recorded more significant improvements when compared with those in the ASMP. Measures such as the VAS pain and the WOMAC indicated that the OAK Program achieved significant improvements when compared with the ASMP to final follow-up at twelve months. Of particular interest was the apparent level of dissatisfaction reported anecdotally by those allocated to the ASMP group.

The following discussion will present the findings of each of the studies in turn, examining the variables of interest in detail and comparing findings with other published literature. Consideration of common components of the two studies will follow, indicating how the sequence of the studies adds to the understanding of the value of SM in the long term treatment of OA of the knee. Subsequently, limitations of the studies will be considered to examine issues that may need to be considered when attempting to generalize the study findings. In the light of the limitations identified, suggestions for further

research that could add to the development of knowledge in this area will be identified.

Study 1

Random assignment to the OAK Program or a Control Group

A randomised controlled study compared the OAK SM Program with a control group that did not participate in the program but continued with their routine care. The participants in both groups were followed to 6 months post intervention. At the end of the follow-up period, those in the control group were offered the opportunity to participate in an OAK Program.

Hypothesis

To determine whether a disease specific SM program for people with osteoarthritis of the knee (the OAK Program), implemented by health professionals, would achieve and maintain clinically meaningful improvements in health related outcomes compared with a control group.

Primary outcome measures included WOMAC, SF-36 questionnaire, VAS pain and TUG. Secondary outcomes included active ROM of the knee joint using a long-armed goniometer, and quadriceps and hamstring strength measured using a fixed Mecmesin dynamometer.

To test the effects of treatment, between group differences in changes over time (baseline, 8-weeks and 6-months) were examined using repeated measures ANCOVA. In addition, response to treatment was determined using responder criteria as defined by OMERACT-OARSI, scenario D (Pham, van der Heijde et al. 2004). Furthermore, the proportion of participants achieving minimal clinically important improvements (MCII) independently in health status, quality of life, pain, and the TUG test were computed for each group at each observation time and Chi-square tests were used to examine proportions between groups.

MCII is becoming more prevalent as an additional means of expressing improvement that is a result of treatment. It focuses on the patient's perspective of the minimal change needed for improvement. Kvien, Heiberg et al (2007) describe MCII as the smallest change in measurement to detect an improvement (Kvien, Heiberg et al. 2007). Tubach, Ravaud et al (2005) suggest that using MCII provides readers with clinically meaningful information on the effect size by expressing the results (usually) as a percentage of improved patients which is more easily understood than conventional p values (Tubach, Ravaud et al. 2005). However, the concept aims at complementing traditional effect size reporting, not to replace it.

Mean differences

Pain was measured using three variables: WOMAC, SF-36, and VAS. Each of these outcome measures independently demonstrated a significant improvement in pain from baseline to 6-months in the OAK group compared with the control group.

WOMAC Pain, Physical Function and Total scores improved significantly more in the OAK group when compared with the control group. The advantage in between-group difference in change was evident at post-treatment and 6-months follow-up in the Physical Function and Total scores, however the magnitude of improvement in pain though significant was slightly less between groups by 6-months. In the OAK group WOMAC Pain was significantly decreased post intervention with a plateau effect at 6-months. The control group had almost no change in WOMAC Pain at 8-weeks with only a very slight improvement at 6-months. The decrease in pain noted in the OAK group appears to be unique among previously reported arthritis SM programs (Warsi, Wang et al. 2004; Bury, Newbould et al. 2005; Chodosh, Morton et al. 2005).

Similar improvements were significant in SF-36 Body Pain from baseline to 8-weeks in the OAK group compared with the control group and these differences were maintained at 6-months. In the OAK group, VAS pain decreased 30% during the 8-week intervention, while the control group had

an 18% increase in pain during the same period. These findings are of particular interest in light of Bombardier et al (1995) comparisons of two of these measures.

Bombardier, Melfi et al (1995) compared the disease specific WOMAC Pain and Physical Function domains with the generic SF-36 Body Pain and Physical Function dimensions to examine the characteristics of disease specific and generic instruments (Bombardier, Melfi et al. 1995). The authors noted that people who were free from pain in WOMAC Pain scores continued to experience pain and physical disabilities due to co-morbidity, when measured on the SF-36 instrument. This was expressed by lower SF-36 scores (Bombardier, Melfi et al. 1995). The suggestion made is that WOMAC is more sensitive to disease specific pain than SF-36, and the SF-36 discriminates better between general health status and co-morbidity due to other conditions. Bombardier, Melfi et al (1995) concluded that disease specific instruments are essential in determining improvement due to specific interventions whereas generic instruments are important in determining general health and function (Bombardier, Melfi et al. 1995).

VAS pain showed a marked improvement at week three of the intervention in the OAK group and this coincides with an increase in exercise expectation in the OAK Program. At the beginning of the Program, participants were encouraged to incorporate “incidental” exercise into their daily routines. This incidental exercise included behaviours such as using stairs instead of elevators, walking to the shopping centre, parking further away from the entrance of the shopping centre, walking as an alternative to driving short distances and other short exercises designed to become “habits” of physical activity. In addition, by week three in the OAK Program participants were expected to have an established formal exercise regimen that could be added to and consolidated for the remainder of the Program. By the completion of the Program, ideally participants would have a structured exercise regimen as well as incorporating exercise habits into their daily routines. The increase in physical activity along with the positive results

noted above are likely to support the assumption that physical function improved as a result of the OAK Program.

The current findings of significant and maintained decrease in pain are of particular relevance, since pain has been identified as a major contributing factor to the loss of function and increase in dependence among people with OA (McCarthy, Mills et al. 2004). According to Nuesch, Dieppe et al (2011) pain and loss of function together are associated with increased mortality above and beyond that of people with OA knee who themselves have a greater risk of mortality than the general population.

In contrast to the present findings, Warsi, LaValley et al (2003), in a meta-analysis of the effect on pain and disability of arthritis SM programs, describe the reductions in pain as being small (Warsi, LaValley et al. 2003). Warsi's study did not account for the heterogeneity between the studies in their meta-analysis, and a subsequent systematic review by Warsi, Wang et al (2004) found that arthritis SM programs were not associated with statistically significant effects (Warsi, Wang et al. 2004). Chodosh, Morton et al (2005) in their meta-analysis of SM programs also found that OA SM programs do not appear to have a clinical effect on pain or function (Chodosh, Morton et al. 2005). Considering that the participants in Study 1 were homogeneous, that is they all had OA of the knee, the improvements in pain demonstrated are quite unique in SM for OA.

Newman and Mulligan (2004) did note one exception to this general finding in one study that translated the ASMP into Spanish. However it was not a direct translation of the ASMP and also included other aspects as well as a formal exercise component (Lorig, Gonzalez et al. 1999). Commenting on this study in their meta analysis of SM, Newman and Mulligan (2004) suggest that the exercise component might be a crucial aspect in OA SM (Newman, Steed et al. 2004), providing support for the present study, since the OAK Program encouraged the participants to find and persist with an exercise program that suited their needs.

A number of aspects of the OAK Program may have contributed to the reduced pain levels reported by participants. Both aerobic and resistance exercise in a home-based exercise program have been shown to significantly reduce knee pain in patients with OA (Thomas, Muir et al. 2002). An important component of the OAK intervention is to encourage the formulation of a comprehensive exercise program that incorporates strengthening, endurance and flexibility components. In accordance with SM principles, participants are motivated to use this information when planning their weekly goals. The use of goal setting is designed to promote long-term adherence to the exercise regimen.

It is also likely that the OAK intervention facilitated better pain-coping skills that are important predictors of disability associated with OA (Steultjens 2000; Huang, Yang et al. 2005). Previous studies have reported that catastrophising and negative self-statements are associated with increased knee pain (Keefe, Lumley et al. 2001). In the OAK intervention, participants are taught strategies for cognitive symptom management such as distraction, guided imagery, relaxation techniques and negative self-talk that are thought to be important additional strategies for pain management in people with OA (Messier, Loeser et al. 2004; Kidd, Langford et al. 2007).

Pain management is an important concept because many people with OA are hesitant to undertake new activities for fear of pain. As well as exercise instruction and cognitive therapies, within the OAK Program medication usage and therapeutic dosing principles with particular emphasis on analgesia were taught to encourage medication compliance and effective pain management. The average age of participants was 65-years and most had several co-morbidities requiring medication. Many participants had an aversion to medications and would delay taking analgesia until their pain became acute and therefore more difficult to control. Pain management principles were discussed to educate participants about their pattern of pain and the appropriate treatment response eg: “around the clock” analgesia dosing for acute pain, or “as needed” analgesia for intermittent pain.

The combination of health professionals modelling exercises and goal setting together with the knowledge and reassurance of attaining adequate pain relief specific to the OAK Program, was designed to encourage participants to participate in appropriate physical activity and exercise that previously may have been considered by participants to be beyond the scope of someone with OA of the knee. Additionally, health professionals were available for reassurance, counselling and trouble shooting should participants experience problems with exercise or pain control during the Program.

Similar improvements were evident for Stiffness, which is the least sensitive of the WOMAC domains. As with Stiffness, Physical Function improved significantly in the OAK group at 8-weeks and this improvement was maintained until 6-months. The control group showed no improvement at any time-point. This same pattern was evident in WOMAC Total scores.

The WOMAC was developed using specific questions regarding sources of discomfort and disability in OA of the knee and/or hip. It was designed to assess symptoms that occur commonly, are thought of as being important, and are experienced on a daily or weekly basis. Thus it aims to monitor and detect change in clinically important events that recur frequently and are regarded as important to symptomatic people with OA of the knee/hip (Bellamy 2002). Of the five “pain” questions, three refer to pain with physical activities such as walking on a flat surface, going up and down stairs, and standing upright. The two stiffness questions relate to the severity of stiffness on wakening, and the severity of stiffness during periods of inactivity. The seventeen physical function questions relate to functional aspects of daily living such as climbing up and down stairs, walking, getting in and out of a car, shopping; dressing, getting in and out of bed, bathing, toileting, and difficulty performing domestic duties (Bellamy 2002). Therefore an improvement in WOMAC scores over time would suggest that every day functional activities are more manageable as a result of the intervention being tested.

Few arthritis SM programs are disease specific thus WOMAC is not a standard measure utilized in many SM studies since it is specifically designed for OA knee and or hip. Therefore it is difficult to compare our WOMAC improvements with other SM RCTs. As stated earlier, WOMAC is more sensitive than SF-36 for OA and is considered to be the best determinant for physical impairment (Pollard, Johnston et al. 2006). This suggests that evidence of improvement in the OAK group in all WOMAC domains in addition to improvements in SF-36 Physical Function and Body Pain, VAS pain, ROM, quadriceps and hamstring strength and TUG is likely to equate to a functional improvement. Again, considering the findings of Nuesch, Dieppe et al (2011), that improving physical function is likely to reduce mortality in people with OA of the knee (Nuesch, Dieppe et al. 2011), this is an important outcome.

The SF-36 questionnaire has eight dimensions that are designed to capture the following health concepts: behavioural functioning, perceived well-being, social and role disability and personal evaluations of health in general (Ware, Kosinski et al. 2002). Four of the dimensions relate closely to physical health with the remaining four relating to mental health status. It is accepted that the physical health dimensions are more relevant to people with OA (Ware, Kosinski et al. 2002). These four dimensions include: Physical Function, Role Physical, Body Pain and General Health. Physical Function assesses limitations in performing all physical activities including bathing or dressing thus it measures limitations in behavioural performance in everyday activities. Role Physical determines difficulties with work or other daily activities as a result of physical health. It measures the extent of disability in everyday activities due to physical problems. Body Pain assesses pain or limitations in activities due to pain. General Health evaluates personal health status and the prospect of it becoming worse and has been linked to several indicators of health expenditure, namely hospitalisation, visits to medical practitioners, and prescriptions per visit. Those with poorer General Health scores tend to have greater utilization than those with higher scores. Vitality assesses tiredness and energy all of the time. Social Functioning determines the level of interference due to physical or emotional problems with normal

social activities. Role Emotional evaluates interference by emotional problems with work or daily activities. Mental Health determines the extent of nervousness and depression, or peacefulness, calmness and happiness all of the time (Ware, Kosinski et al. 2002). Although these dimensions are not disease specific to OA knee they are important predictors of general health response to treatment especially if they are concordant with the results from disease specific measures.

There were significant improvements from baseline to 8-weeks in five of the eight dimensions in the SF-36 scales: Physical Function, Role Physical, Body Pain, Vitality and Social Function, in the OAK group compared with the control group. These differences were maintained at 6-months. A difference of 5 points is considered to be clinically relevant in arthritis populations (Ware, Kosinski et al. 2002) and this was demonstrated in Physical Function at both 8-weeks and 6-months; Role Physical at 8-weeks and 6-months; Body Pain at both time-points; Vitality at 8-weeks; and Social Function at 8-weeks. General Health improved in the OAK group compared with the control group at all time-points although it did not reach significance. Scales that load highest on the physical component such as Physical Function, Role Physical, and Body Pain are the most sensitive to physical response to treatment which has implications for reducing mortality in people with OA knee (Nuesch, Dieppe et al. 2011) and are also the most responsive to knee replacement (Ware 2004). Although this study is not concerned with knee replacement, many of the symptoms would be common to people with OA of the knee.

The SF-36 is a generic instrument that also captures health status symptoms of co-morbidities (Bombardier, Melfi et al. 1995). Considering that people over the age of 60 are likely to have more than one co-morbidity (Kadam and Croft 2007) it is probable that this instrument also captured adverse health symptoms other than OA of the knee. The interaction of co-morbidities and OA was discussed in the literature review that highlighted the compound effect of OA plus another co-morbidity (Kadam and Croft 2007). Considering the significant improvements in five of the eight SF-36 dimensions (three of

the physical health dimensions) it is reasonable to suggest that the OAK program has had a beneficial effect not only on OA knee but also on general health and health issues relating to co-morbidities.

TUG results showed a significant improvement in the OAK group compared with the control group post-intervention and at 6-months. An MCII for TUG was observed in three times as many OAK group participants as control group participants at 8-weeks (OAK: 46 and control group: 15) This finding remained statistically significant at 6-months, but it had shown some decline relative to the value recorded for the control group (OAK: 38 and control: 26).

The TUG normal value for people 60-69 years of age to walk three meters outbound and three meters return is nine seconds and it is suggested that slower times may warrant physical interventions (Bohannon 2006). However in this study an extra 15cm step in the outbound walk was added that would potentially add time to the exercise. Thus, neither group were expected to approach the normal value at baseline. Post intervention the OAK group mean (SD) was 9.8 (0.17) seconds (approaching the norm) and by 6-months it was 10.1 (0.23) seconds. By contrast, the control group post intervention was 11.2 (0.17) seconds and 10.8 (0.23) at 6-months. Thus, even with the added step task, the intervention group showed improvement at the first time point and very little decline at the 6-month time point, when compared with the control group.

Small increases in ROM were observed. Extension in both knees, and flexion in the left knee in the OAK group improved significantly compared with the control group. It is difficult to determine what constitutes a clinical improvement in ROM as it is not defined in the literature, and rather than a finite quantity, recommendations for improving ROM in patients with OA knee are based on expert opinion (Richmond, Hunter et al. 2009). However, it is known that ROM is affected by OA of the knee and that improvement in ROM in combination with increased lower limb muscle strength equates to improved functional mobility and activities of daily living such as walking,

getting in and out of a bath, rising from a chair, gait speed and falls efficacy (Beissner, Collins et al. 2000; Steultjens 2000).

Hamstring strength improved significantly in both right and left legs in the OAK group compared with the control group. The significant improvement demonstrated in the OAK group post intervention in the right hamstrings was 34% and was maintained at 6-months with a 29% improvement. In the control group, similar improvements of 10% post intervention and 14% at six-months were achieved. Similar improvements were observed with the left hamstrings. There were also improvements in both left and right quadriceps strength in the OAK group, although these improvements were not significant between groups. In contrast the control group left quadriceps strength diminished in both legs post intervention and at 6-months with the exception of the right leg that had a very small non-significant improvement.

There is a reliable association between WOMAC and physical function tests such as ROM, muscle strength and TUG (Lin, Davey et al. 2001) making the combination of WOMAC and physical measures useful for the evaluation of therapeutic interventions that may have an affect on activities of daily living that influence disability (Beissner, Collins et al. 2000). As previously noted on page 27 by Liu and Latham (2009), improved muscle strength has a positive effect on pain and function. Furthermore, as highlighted in the literature review on page 19, decline in lower limb muscle strength and ROM are predictors of decrease in functional ability (Beissner, Collins et al. 2000; Steultjens 2000). Therefore these results support the suggestion that physical functioning is likely to have improved as determined by improvements in WOMAC, SF-36, VAS and physical outcome measures particularly ROM and muscle strength and importantly, these improvements were maintained over time.

This is particularly relevant in light of evidence of increased mortality in people with OA of the knee as suggested by Nuesch, Dieppe et al (2011). As presented in the literature review on page 25, the most striking finding of that study was that those people with OA of the knee and a walking disability are

at an even greater risk of early death than their more active counterparts leading the authors to suggest than an aggressive approach to encouraging physical activity even with painful OA seems justified (Nuesch, Dieppe et al. 2011). These suggestions are in concert with the constructs of the OAK Program.

A favourable response to treatment (responder) was as defined in the OMERACT-OARSI criteria scenario D (Pham, van der Heijde et al. 2004). However, since global health was not collected in Study 1 it could not be included. Therefore only improvements in pain, and WOMAC Physical Function were used for classification of a responder. Following the intervention, the significant proportion of responders at eight weeks in the OAK group was more than three times that of the control group. At this post-treatment assessment 26 (39%) people from the OAK group and eight (12%) from the control group were classified as responders. Again there were more responders in the OAK group 22 (33%) than in the control group 14 (20%) at six months, however the difference between groups was not statistically significant at this time-point.

There is some conjecture about the most appropriate point score that constitutes an MCII for the SF-36. The developers, Medical Outcomes Trust, suggest that a five point difference is clinically relevant (Ware, Kosinski et al. 2002) however Angst et al (2001) suggest that a range from 3.3 to 5.3 points for Physical Function and 7.2 to 7.8 points for Body Pain dimensions are relevant for OA of the knee or hip (Angst, Aeschlimann et al. 2001). For both Study 1 and 2, a five-point difference in both SF-36 Pain and Physical Function domains was chosen to represent MCII.

The OAK group had a greater proportion of MCIIs in all outcome measures at all time-points when compared with the control group. The differences were significant for WOMAC Physical Function, SF-36 Physical Function, VAS pain and TUG at eight weeks. At six months the differences in WOMAC Physical Function MCII and TUG were significant (VAS pain data were not collected at six months). The OAK group achieved more MCIIs than the

control group, but the differences between groups in SF-36 Physical Function and SF-36 Body Pain were not significant at six months. Significance aside, 60% of the OAK group achieved MCIIs in SF-36 Physical Function at both eight weeks (significant) and six months (not significant) compared with the control group that achieved 34% and 22% at the same time-points. This is an important improvement as it may well equate to a reduction in mortality in the long term (Nuesch, Dieppe et al. 2011). The proportion of MCIIs between the OAK and the control group was greatest immediately post intervention, OAK: 215 and control: 83. In the OAK group more than 2.5 times as many participants were observed to achieve a MCII compared with the control group at eight weeks and more than a third more at six months.

The number of MCIIs the control group achieved increased from post-intervention to 6-months. It is difficult to explain this improvement other than an interaction with health care providers having clinically useful effects (Hrobjartsson and Gøtzsche 2004), and possibly the Hawthorne effect that describes control groups improving simply because of participation in a trial (Adair 1984).

There are no published results of arthritis SM that evaluate responder or MCII criteria as outcome measures so it is difficult to speculate whether the responder and MCII improvements demonstrated in Study 1 are replicated in other studies. However, the significant improvements in the OAK group in WOMAC, SF-36, VAS pain, quadriceps and hamstring strength, ROM and TUG, in addition to the number of responders and MCIIs in the OAK group further strengthens the assertion of an improvement in function in the OAK group.

The control group had improvements in some outcomes that need to be explained. The most likely explanation is the benefit this cohort of people derived from the patient health care provider interactions at the various assessment points. In addition, this cohort continued with their regular treatment regimen and could well have shown improvement as a result of this ongoing care. Thus patients in the untreated control group were likely to

have interacted with health care providers and the possibility of patient-provider interaction could have clinically useful effects (Hrobjartsson and Gøtzsche 2004). Furthermore, this interaction can influence patients' beliefs about their illness or treatment. By providing support, empathy, care and reassurance, the fear and anxiety that patients feel may be lessened and it may also improve the way they perceive their illness (Di Blasi, Harkness et al. 2001). There may have been a Hawthorne effect explaining in part the improvements seen in the control group (Campbell, Maxey et al. 1995).

Summary of Study 1

In summary, the significant improvements in pain, quality of life and function among the subjects in the experimental group when compared with the control group were such that further investigation was warranted. Since Study 1 employed no treatment control group, it was therefore important to investigate whether the benefits of the OAK Program would be the same if the control group were enrolled in an alternative SM program such as the ASMP.

Both Weingarten, Henning et al (2002) in their meta-analysis of chronic disease management programs and Newbould, Taylor et al (2006) in their review of lay led self-management suggest that comparison of different programs is necessary to determine effective SM programs. In Study 2 we will make such a comparison.

Study 2

Random assignment to the OAK Program or the ASMP Group

The second study was a RCT that compared the OAK Program with the ASMP with follow-up to 12-months. The hypothesis stated: A greater proportion of people with osteoarthritis of the knee that complete the OAK will achieve a minimal clinically important difference in pain, function and quality of life, at eight weeks, six and twelve months compared to those who complete the ASMP.

Participants and assessors were blind to group allocation. The primary outcomes for Study 2 as described in the ACTR registration were WOMAC, SF-36, and VAS pain. The secondary outcomes included the Arthritis Self-Efficacy scale, step test and single leg timed balance. Amendments to the study protocol included the addition of TUG, VAS global health and VAS global improvement. This was necessary to meet OMERACT-OARSI criteria (Pham, van der Heijde et al. 2004). Between group differences in changes over time using repeated measures ANOVA were examined, and additionally the proportion of participants achieving MCII and responder criteria was computed for each group at each observation time and Chi-square tests were used to examine proportions between groups.

Primary Outcomes

WOMAC ANOVA

Participants in the OAK Program had significantly greater improvements compared with those in the ASMP from pre-intervention to twelve months in WOMAC Pain, Physical Function and Total scores. While there was improvement recorded in stiffness among those in the OAK group compared with the ASMP group, this difference was not significant.

As considered in Study 1 on page 127, these results are important in relation to function and disability since pain is a major contributing factor to the loss of function and increase in disability in people with OA of the knee (McCarthy, Mills et al. 2004). The WOMAC measure is particularly relevant to our OA of the knee population as it measures pain related to physical activities. Thus the combination of an improvement in WOMAC Pain, Physical Function as well as the Total score domains is highly suggestive of an improvement in functional abilities in the OAK group compared with the ASMP group. Moreover, these significant improvements were maintained to 12-months. In light of the findings by Nuesch, Dieppe et al (2011) with respect to pain and walking disability and the association with increased mortality, an improvement in these measures is highly significant. These authors stress the importance of OA treatment programs that target

strategies to improve physical activity and thereby reduce the risk associated with increased mortality (Nuesch, Dieppe et al. 2011).

The improvements in WOMAC Pain, Physical Function and Total domains have not previously been demonstrated in arthritis SM programs and are therefore unique to the OAK Program. Furthermore, these improvements in WOMAC outcomes were consistent through out the three studies testing the OAK Program- the Quality Assurance study, Study 1 and Study 2, and they were maintained long term.

WOMAC MCII

A greater number of MCIIs in WOMAC pre to post-intervention was recorded for the OAK Program participants than for the ASMP subjects. Since a MCII reflects the patient's perspective of improvement, these results present another way of observing the same improvement in pain and function seen in the ANOVA analysis that further strengthens the assertion of a greater improvement in physical functioning in those people in the OAK group compared with the ASMP group. These improvements were maintained at all other time-points although not necessarily at the same level, since some of them became non-significant.

Responders

The mean change in pain intensity is not always the easiest method of interpreting treatment results. OMERACT-OARSI developed the responder criteria to encourage the uniform reporting of results in clinical trials (Pham, van der Heijde et al. 2004). Responder criteria are based on improvements in pain, WOMAC Physical Function and Patient Global assessment and aim to determine an individual's response to treatment.

The number of the OAK group responders was greater than the ASMP group responders at all time-points, however this difference was only significant at the post-intervention time-point. Post-intervention almost half the OAK group were classified as responders compared to almost one third of the ASMP group. This significant result suggests that half the OAK group had a clinical

response to treatment (the OAK Program). Since responder criteria includes the assessment of pain and function which has a relationship with disability and dependence (McCarthy, Mills et al. 2004), this measure is an important determinant of functional improvement. Importantly, improved function is associated with reduced mortality risk as described by Nuesch, Dieppe et al (2011). Thus even when not significant, those in the OAK group were more likely to be responders than those in the ASMP group with the advantage in the OAK group maintained albeit to a lesser degree at the later time-points.

SF-36 ANOVA

The significant improvements seen in the OAK group when compared with those in the ASMP were also demonstrated in the SF-36 ANOVA analysis pre-intervention to twelve months. These significant improvements were demonstrated in the primary outcomes of SF-36 Physical Function and General Health, both of which are classified as physical dimensions. Physical Function assesses limitations in performing all physical activities including bathing or dressing and it measures limitations in behavioural performance in everyday activities due to health. General Health evaluates personal health status and the prospect of it becoming worse. As discussed on page 130, poorer General Health scores are linked to several indicators of health expenditure, namely hospitalisation, visits to medical practitioners, and prescriptions per visit and indicate greater utilization than those with higher scores (Ware, Kosinski et al. 2002).

As noted on page 130, SF-36 physical dimensions are more specific to OA knee (Ware 2004) therefore an improvement in the SF-36 Physical Function and General Health dimensions in the OAK group compared with the ASMP group at all time-points adds strength to other findings that support a functional improvement. Again, this improvement in function directly relates to disability, independence and mortality risk (McCarthy, Mills et al. 2004; Nuesch, Dieppe et al. 2011). The significant improvements demonstrated in the OAK group compared with the ASMP group were significant post-intervention and were maintained long-term to 12-months.

SF-36 MCII

As with Study 1, for this analysis, a five-point difference in both pain and physical function domains was chosen to represent MCII was chosen.

The OAK group demonstrated significant MCIIs in SF-36 Physical Function post-intervention. At this time-point 70% of the OAK group achieved MCIIs in SF-36 Physical Function, and at six and 12-months this percentage was only slightly decreased. The OAK group demonstrated more MCIIs in SF-36 General Health at all time-points than the ASMP group, with significance at six and 12-months and approaching significance at post intervention. To reiterate, improvements in these SF-36 domains reflect functional improvement in activities of daily living and perceived health status and reflect improvement (or deterioration) in these domains (Ware, Kosinski et al. 2002).

Again the OAK group compared with the ASMP group demonstrated the repeating scenario of improvement in pain and functional outcome domains which may well translate to improved functional ability and less dependence with an associated reduction in mortality risk (Fransen and McConnell 2008; Nuesch, Dieppe et al. 2011).

VAS Pain ANOVA

The ANOVA result that compared the VAS Pain mean scores of the two groups (OAK and ASMP) were of particular interest, since, as for Study 1, they showed that those in the OAK group recorded significantly less pain than those in the ASMP group.

VAS pain demonstrated a more dramatic difference in pain scores between the two groups than other pain variables. The OAK group showed a small increase in pain until week three followed by a steady reduction in pain for the duration of the intervention and continued to decrease until six months when there was a plateau effect. This same pattern of improvement seen in the OAK group at week four has previously been observed in both the Quality Assurance study and Study 1 (Coleman, Conroy et al. 2002;

Coleman, Briffa et al. 2008a). In contrast, among those in the ASMP group there were fluctuations in pain but no consistent pattern from pre to post-intervention.

VAS Pain MCII

Additionally, those participating in the OAK Program demonstrated more MCIIs in VAS pain criteria than ASMP participants at all time-points, although these were not significant. However, even when not significant, improvement in MCII VAS pain in the OAK group when compared with the ASMP group was consistent with improvement in other pain variables and reflects the same improvements seen in the ANOVA analysis.

Across the three studies in which the OAK Program has been examined (Coleman, Conroy et al. 2002; Coleman, Briffa et al. 2008 and the present report) a reduction in pain has been a consistent finding. This finding provides solid support for the value of the OAK Program and the use of a disease specific SM program for people with OA of the knee led by health professions. Since no other reports in the literature suggest that pain relief is a finding in SM programs for people with OA of the knee, this series of findings add a new dimension to the discussion of SM programs for OA of the knee. Furthermore, it supports the assertion that the combination of improvements in physical function and pain variables are associated with improved function in people with OA of the knee (Fransen and McConnell 2008).

Secondary Outcomes

None of the secondary outcome measures indicated significant differences between the two groups of participants. Both the OAK and ASMP groups had small improvements over time in self-efficacy. However as for other outcomes, between group differences were not significant. The small magnitude of the improvement is surprising particularly in the ASMP group as the premise of the ASMP is that SE rather than the acquisition of knowledge and skills results in improved health outcomes (Marks and Allegrante 2005; Taylor and Bury 2007) and previous trials of the ASMP

report improvements in SE (Lorig, Lubeck et al. 1985; Lorig, Feigenbaum et al. 1986; Lorig, Mazonson et al. 1993).

Summary of Study 2

In summary, in Study 2, while the participants in both the OAK and ASMP groups demonstrated improvements in most outcomes over time, those in the OAK group consistently demonstrated more statistically significant improvements when compared with the ASMP group. The VAS pain and WOMAC measures clearly demonstrated that participants in the OAK Program achieved significant improvements when compared with those in the ASMP to 12 months. Other outcomes were less decisive. For example, although the OAK group achieved a greater number of responders and MCIIs than the ASMP group, only a few differences were significant. Those in the OAK group had greater improvements in almost all the methods used to measure pain and were statistically significant in the ANOVA VAS analysis with WOMAC Pain approaching significance at 12 months. The number of OAK group responders was significantly greater than that for the ASMP post-intervention, and were maintained over the follow-up period however as time progressed they became non-significant.

The improvements demonstrated in the OAK group compared with the ASMP group in pain and physical function measures are important, as these are predictors of disability and function. The improvements in these measures suggest a functional improvement and in the context of the findings of increased mortality associated with a decline in functional ability by Nuesch, Dieppe et al (2011) this is a very significant association.

Outcomes of Studies 1 and 2

There was a sharp decrease in VAS pain in the OAK group during the third week of the intervention and this pattern was repeated in both Studies 1 and 2. This coincided with an increase in the exercise component of the OAK Program that has been described previously in Study 1 discussion on page

123. Of note, this same pattern of pain decrease was also demonstrated in the earlier QA study (Coleman, Briffa et al. 2008a).

It has been suggested that there is no clear evidence that demonstrates the mechanisms involved in successful SM (Newbould, Taylor et al. 2006). It may be that success is due to the structured nature of the intervention or perhaps more non-specific mechanisms such as group dynamics are involved. There is even a suggestion that the improvements demonstrated in SM interventions are due to the participants involvement rather than the intervention itself (Taylor and Bury 2007). That there is no clear-cut relationship between behaviour change and other outcomes has been demonstrated in studies where behaviour has changed but clinical outcomes have not (Newman, Steed et al. 2004). Most arthritis SM programs include heterogeneous cohorts so there are confounding elements that may interfere with this relationship. However, in both Study 1 and Study 2 all the participants had OA of the knee and it may be that this created the necessary environment for change in behaviour to correlate with the change in clinical outcomes that have been identified. It may be that those heterogeneous arthritis SM programs in which participants have variety of musculoskeletal conditions have different requirements and needs that are not being met by a generic program.

It is often assumed that SE is the central component of successful SM. However there is no evidence that indicates the extent to which SE is an independent variable relating to SM. Moreover, it is unclear whether high levels of SE are a consequence rather than a cause of SM (Taylor and Bury 2007). Yet most SM trials include SE measures among their primary outcomes. Neither the OAK group nor the ASMP group demonstrated significant between group changes in SE at any time-point and the small within group improvements were equivalent in each group. Since the tenet of ASMP is based on SE theory this is difficult to explain (Lorig and Holman 2003). The result of minimal change in SE in the ASMP group is inconsistent with other studies of SM using the ASMP as they routinely report improvements in SE (Lorig, Mazonson et al. 1993; Barlow, Turner et al.

1998; Lorig, Gonzalez et al. 1999; Barlow, Turner et al. 2000). One such study (Lorig, Mazonson et al. 1993) reported improved SE despite worsening in levels of disability. This is an important area that warrants further research.

Lay leaders are an integral component of the ASMP although there is little evidence to support this model of SM in preference to utilizing health professionals with more disease specific programs (Taylor and Bury 2007). The argument for the use of lay leaders centres on the premise that lay leaders are patient "experts", and that the essential component of SM is to promote SE rather than to educate or impart disease specific skills to the participants (Newbould, Taylor et al. 2006). Taylor and Bury (2007) in their review of chronic illness and SM suggest that not withstanding possible cost advantages, lay-led SM interventions may have little effect on chronic illness and they suggest that enhanced professional involvement in SM could be beneficial (Taylor and Bury 2007). With this in mind, the comparison of a generic lay led SM program (the ASMP) with a disease specific SM program delivered by HP's (the OAK Program) with a homogeneous cohort of participants is of particular importance especially since it has not previously been done.

Lay vs Health professionals

The OAK Program is designed to be disease specific and use the knowledge and skills of health professionals to deliver a program that incorporates detailed information and education on OA of the knee within SM constructs. In this respect it is unique among SM programs for arthritis. As Newbould et al (2006) in their review of lay led SM have reported, the development of condition specific SM programs delivered by lay leaders has, to date, been very limited (Newbould, Taylor et al. 2006). The specificity achieved by the OAK Program would appear to meet this expectation of Newbould, Taylor et al. (2006) and give the program weight. The success of this endeavour is further indicated by the improvement in participant assessment over the period of interest to the studies reported here.

With SM programs that are medication-orientated there appears to be consensus regarding their effect by increasing adherence to medications (Warsi, Wang et al. 2004; Chodosh, Morton et al. 2005). This is demonstrated by the significant effects seen in asthma, hypertension and diabetes SM programs (Chodosh, Morton et al. 2005) all of which are medication orientated. As explained on page 125 in the Study 1 discussion, in the OAK Program syllabus, pharmacological therapy and pain relief are a central component. This was reflected in the QA study as well as Study 1 and Study 2 by a dramatic reduction in pain at the third week of the program that coincided with an increase in structured exercise expectation in the program syllabus.

Pain was significantly reduced in the OAK group in outcomes in both studies. Pain management is important because many people are hesitant to undertake some activities for fear of pain, regardless of whether they have previously experienced pain with that particular activity. Many people with OA rely on medication for pain relief but are reluctant to take drugs that may have side effects. Their inclination is to be aware of the pharmacologic and treatment options available and then decide on their course of management (Fraenkel, Bogardus et al. 2004). However, if their knowledge about the available options is lacking, this may incorrectly influence their treatment of choice and importantly, it may have an impact on their adherence to treatment (Mitchell and Hurley 2008). Promoting understanding and agreement between individuals and health professionals on medication adherence reflects the growing awareness of the fact that health professionals need to respect patients' beliefs and decisions particularly with regard to evidence-based practices (Taylor and Bury 2007).

Limitations of Studies 1 and 2

Study 1 compared a treatment program with a non-treatment control group and was therefore unblinded; consequently there is a risk of reporting, attrition, and other types of bias. In addition, self-reporting of pain may be affected by bias, as patients are keen to "do well" and to please health care

providers by reporting an improvement when there may not have been one. Moreover, the perception of the efficacy of the treatment by the health care providers may influence how the patients perceive their pain and result in improved pain ratings (Hirsh, Atchison et al. 2005).

Participants within the control group attended three assessment visits prior to commencing the OAK Program at the completion of the six-month control (waiting) period. Positive expectations of attending the OAK Program may also have contributed to the anticipated benefits of the OAK Program thereby influencing the outcomes during the control period (Turner, Deyo et al. 1994).

Another limitation of Study 1 was the relatively short control period of six-months. A longer control period would have been useful however, although a longer control period was considered when planning the study design, the Advisory Committee thought it would be difficult to recruit participants with a control period longer than six months. In addition, as most participants were self-referred through their GP, there were ethical issues involved in the withholding of treatment for a longer period of time in order to obtain a representative sample (Barlow, Wright et al. 2002; Bury, Newbould et al. 2005), particularly in light of the positive results demonstrated in the QA study (Coleman, Briffa et al. 2008a). Although follow-up assessments continued for 12 months following the OAK Program, they were then "uncontrolled" because of the absence of a comparison group and therefore have not been reported in this thesis.

In both Studies 1 and 2, most enrolments were initiated by participants who approached their own GPs to arrange referral into the study. This self-initiated enrolment may have been responsible for potential bias as those people who volunteered may already be predisposed to SM (Newbould, Taylor et al. 2006; Taylor and Bury 2007) and this behaviour may not be a true reflection of health patterns in the community.

The participants enrolled in Studies 1 and 2 were over represented from higher socio economic groups and therefore the results may not be a true

reflection of the likely impact on the wider community as there is the potential for people with higher education levels to show greater improvements.

In addition to the limitations noted above, Study 2 had a high attrition rate. In the previous quality assurance study, the drop out rate was below 10% and rose to 17% in Study 1. Assuming that this RCT would be similar, the power calculations for Study 2 allowed for a drop out rate of 20%. Although both groups had non-attendees at follow-up assessments it was especially problematic in the ASMP group. The attrition rate was 26% in OAK and 44% in ASMP at 12-months that was reduced to 15% and 25% respectively when the data from posted questionnaires were utilized. However, the posted responses consisted of self-reported questionnaires and did not capture physical assessments such as balance and TUG tests.

Using an intention to treat study design, we employed last value carried forward (LVCF) for other missing data. LVCF assumes that the participant's responses would have been constant from the beginning to the end of the study and this can result in a false conclusion that a difference exists when in fact there is none (Mallinckrodt, Sanger et al. 2003). Furthermore, OA is a condition that generally deteriorates over time. Employing LVCF creates in an impression that the participant is in a state of equilibrium- neither better nor worse; an outcome that could be perceived as beneficial in terms of disease progression in OA leading to bias of the estimates of treatment effect (Baron, Boutron et al. 2005).

In keeping with an intention to treat study design, attempts were made in both studies to retain the study population. This included telephone and written notification of scheduled follow-up assessments; offers to reschedule missed assessment appointments at the convenience of the participant with telephone contact to encourage attendance of assessments missed.

Despite these endeavours there were some participants who did not attend follow-up assessments. All non-attending participants received posted self-reported questionnaires with postage paid self-addressed envelopes

enclosed. Some, though not all, returned the questionnaires and other missing values were recorded with the last value carried forward, which is consistent with an intention to treat analysis.

There was discordance between the number of participants attending assessments post intervention and improvements demonstrated at the same time-points. As attendance dropped (most dramatically between six and 12 months), the number of responders and MCIIs increased, especially in the ASMP group. Considering the drop out rate in the ASMP group at 12 months was 44%, with posted questionnaires this was reduced to 25%, it is difficult to interpret the increase in the number of MCIIs as a treatment effect rather than an overestimation. In addition if there are an unequal number of drop-outs in both groups this can also result in bias in either under or over-estimation of treatment effects (Liu-Seifert, Zhang et al. 2010).

The degree of attrition experienced in Study 2 has been reported in other SM programs with attrition rates of 30 – 50% (Biller, Arnstein et al. 2000; Newman, Steed et al. 2004; Bury, Newbould et al. 2005; Rooks, Gautam et al. 2007). Furthermore, despite the high attrition rate, non-completion may not necessarily equate with lack of benefit (as in medication based trials) especially if the attrition occurred during the follow-up period of the study, which was generally the case in Study 2.

Similar sentiments have been described by Kerns and Rosenberg who report a significant drop out rate associated with SM programs that are CBT orientated (Kerns and Rosenberg 1999). This dissatisfaction was not anticipated and was therefore not assessed as part of the study, however this is an area that may benefit from further research. The ability to identify those people who respond to different models of SM would have the potential to be beneficial in terms of participant satisfaction, attrition, clinical improvements and cost effectiveness.

Four different lay leaders all of whom were accredited ASMP leaders facilitated the ASMP group. The senior lay leader was very experienced and

was the dominant facilitator who participated in every ASMP group. A possible limitation to Study 2 is that this lay leader had attended a previous OAK Program and was therefore not OAK Program naïve and this may have influenced her facilitation. Although instructed to adhere to the ASMP facilitators manual there were occasions when this was not the case. There were discrepancies with additional exercise instruction delivered to the groups that were not scripted in the ASMP manual. Despite counselling to adhere strictly to the ASMP script it was apparent that at times this did not occur.

Future Research

In Study 2 both groups demonstrated improvements despite the dissatisfaction of some of the ASMP group participants. The level of dissatisfaction among some of the ASMP participants made follow-up assessments difficult. It appears that any one particular type of SM model is not going to be suitable for generalised application. There are those people who want specific information including facts and skill based interventions and those others who respond to support group or more, generic interventions. To be able to identify those people who benefit from support group style SM would enable better distribution of health expenditure by screening and allocating people to the type of SM style that suits them best – either generic or disease specific. There is no literature available to suggest that this concept has been investigated.

The central processes underlying successful SM are equivocal. As discussed previously, SE is seen as the fundamental basis of most arthritis SM programs, yet there is little evidence to support this sentiment (Taylor and Bury 2007). It may be that focusing on improving SE as the pivot of the SM intervention is misdirected. Research is needed to establish the mechanisms behind successful SM and to structure SM programs accordingly.

Having established that the mechanisms of successful SM are not well understood (Taylor and Bury 2007), trials that study SM may be relying on

outcome measures that are inappropriate for these types of interventions and are more suitable for medication based clinical trials. Currently accepted outcome measures may not be capturing the underlying process that is responsible for the SM treatment response.

Interventions that require long-term adherence and changes in behaviour have notoriously high attrition rates (diet, exercise and SM interventions) (Roddy, Zhang et al. 2005). With OA, a condition that is expected to deteriorate over time, adherence to treatment interventions is essential and strategies to encourage long-term compliance would be extremely beneficial.

Conclusion

SM may be regarded as an interface between the biomedical model and health psychology by combining information and contributions from both disciplines in an effort to improve the wellbeing of those people with chronic illness (Taylor and Bury 2007). SM may enable individuals with chronic illness, whose main interests are access to treatment and support services, to cope with the challenges of chronic illness.

The OAK Program, a disease specific self-management program delivered by health professionals, demonstrated improvements in pain, function and quality of life in an uncontrolled quality of life study (Coleman, Briffa et al. 2008a). Study 1 of this thesis, an RCT compared the OAK Program with a control group and demonstrated similar results to those achieved in the uncontrolled study. These improvements were maintained to six months (Coleman, Conroy et al. 2002).

In Study 2, a second RCT that compared the OAK Program with Stanford Universities ASMP, similar improvements were demonstrated in the OAK group and to a lesser degree the ASMP group. Most notable among these improvements was the significant reduction in pain and improvement in physical function reported. It should be noted however, that the significance of the differences between groups was relatively small with the exception of

those outcomes that measured pain and the WOMAC Physical Function measures. The reduction in pain experienced was a significant finding throughout this series of studies and is one that has not been reported previously in other studies. Although the OAK Program has demonstrated significant benefits for people with OA of the knee in two separate studies, the results of Study 2 raise questions with respect to the differences in SM programs that require further investigation. In addition, Study 2 did not definitively resolve the question of whether health professional or lay leadership in SM is most effective.

The results of this doctoral work demonstrate that the OAK Program is an effective SM program for people with OA of the knee. Of major importance was the fact that one of the studies provided an RCT with twelve-month follow-up, showing that the improvements gained during the program could be maintained (albeit to a lesser extent) over time. The most consistent finding was related to pain reduction and improvement in physical function that was consistent for both studies and reproduced the finding of the initial quality assurance study.

Based on this work is it possible to suggest that a targeted SM program for people with OA of the knee is superior to routine treatment, particularly with respect to pain reduction and function. It has also been shown that improvements gained during the targeted SM program are likely to be maintained over a six-month period, although decline in these improvements should be noted.

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APPENDIX 1

Study 1 Patient Information Sheet

A Randomised Controlled Trial of an Osteoarthritis Self-Management Program.

Investigators: Dr. Kathy Briffa, Sophie Coleman, Jean McQuade, Dr Charles Inderjeeth.

Introduction
The Arthritis Foundation of Western Australia is testing a new approach to the management of osteoarthritis of the knee. Osteoarthritis is the most common form of arthritis affecting about 10% of the Australian population. People with osteoarthritis of the knee report pain, stiffness, and a decline in quality of life as the disease progresses. Patient education, physical exercise and behavioral modification have been shown to have a positive effect on people with osteoarthritis and therefore we have formulated a program with these three components. We now wish to see how effective this program is for people with osteoarthritis of the knee and will compare it to a control group.

What does the study involve?
In this study we will compare our osteoarthritis program with a no intervention control group. This will involve recruiting people with osteoarthritis of the knee and then allocating them into either the osteoarthritis program or a control group. In order that we don't influence the results of the trial we are using special methods of allocating people to either group. This means that you will not be able to choose which group you are allocated to and you will be assigned to a group by a randomised draw.

The osteoarthritis program consist of 8 two-hour sessions over a period of 2 months. The sessions will be held at the Arthritis Foundation, 17 Lemnos Street, Shenton Park. You will randomised and allocated to either Tuesday morning program or Thursday morning program. The control group will have no intervention and you will be able to continue with your usual medical care. The control group will be expected to attend assessment sessions.

The Program
1. At the first, or baseline, session you will:

- Be asked to complete 4 physical tests:
  - Functional Knee Assessment Test in order to assess your knee function.
  - A quadriceps muscle strength test
  - A hamstrings muscle strength test
  - A knee range of motion assessment

- Be required to complete 3 questionnaires.
  - The WOMAC questionnaire asks questions specific to arthritis of the knee
  - SF36 questionnaire is a general health survey.
  - The VAS is a pain scale in which you rate the severity of your pain.

The information that you give in the questionnaires will not identify you personally and it will be used to assess the effectiveness of the program.

You will also be required to:

- Be interviewed by a registered nurse who will record your current medications, relevant past medical history, date of birth, and photocopy your knee x-ray reports (if you have them). The information provided by you will be kept confidential and not used for any other purpose other than for the purpose of this study. If we are not sure that you have osteoarthritis of the knee we will need you to provide us with your doctor's contact details so that we may ask him/her to confirm your diagnosis.

2. Sessions 2 –6 inclusive
   Consist of 6 group education sessions (one session per week). Each session will run for 2.5 hours. These sessions cover the areas associated with osteoarthritis. At the first session you will be given a course book which you may use for the duration of the program, and throughout sessions 2-6 you will be given information sheets, which you may keep or return.

3. Session 8
   Occurs in the week immediately following the 6 education sessions. At this session the physical measurements and the questionnaires are repeated.

These assessments will be repeated at 6 months

You should not enter this study if you plan to have knee surgery in the immediate future, if you have rheumatoid arthritis or other joint disease, or if you have physical impairments that preclude you from fulfilling the requirements of the program.

Benefits and Risks
The Arthritis Foundation of Western Australia has completed a study of this program and it will be compared to the US arthritis program. The results of this study show that those people who participated had less pain, and experienced improvements in their knee function and quality of life. There were no apparent risks associated with participation in this program or with the US program.

Withdrawal from the study
You may agree to participate in the study but change your mind later. You may withdraw from the study at any time without explanation and in this case your future treatment will not be affected.

Confidentiality and Security of information
Any information about you will be stored in a safe and secure way to prevent others from having access to it. The information provided by you will not be used for any other purpose other than for the purpose of this study. Results of the study may be published in a scientific journal without the use of your name or any other identifying information. The data collected will be kept for 7 years after which time it will be destroyed.

For more information about this study contact:

Sophie Coleman
Arthritis Foundation of Western Australia
17 Lemnos Street
Shenton Park, 6008
Telephone: 9388 2199
Fax: 9388 4488

APPENDIX 2

Study 1 Consent Form

CONSENT TO PARTICIPATION IN A TRIAL OF AN OSTEOARTHRITIS SELF-MANAGEMENT PROGRAM

Investigators: Dr. Kathy Briffa, Sophie Coleman, Jean McQuade, Dr Graeme Carroll, Dr Nicola Cook, Dr Charles Inderjeeth.

I have been given clear written information about this study. I have read and understood it. I have been given time to consider whether I want to take part.

I have been told about the possible advantages and risks of taking part in the study and I understand what I am being asked to do.

I understand that I will be allocated to either a control group or an intervention group using the method outlined in the information brochure.

I understand that if I am allocated to the control group I will be required to wait 6 months before commencing the program, and that if I am allocated to the intervention group I will be required to start the program straight away.

I know that I do not have to take part in the study and that I can withdraw at any time during the study without affecting my future medical care.

I agree to take part in this research study and for the data obtained to be published provided my name or other identifying information is not used.

Name of Participant Date	Participant Signature	
Name of Investigator **Date**	**Investigators Signature**	

Curtin University Human Research Ethics Committee has approved this research study.
If you have any ethical concerns regarding the study you can contact the secretary of the Curtin University Research Ethics Committee on Telephone No. 9266 2784

APPENDIX 3

Study 1 Ethics Approval

MINUTE

Curtin
UNIVERSITY OF TECHNOLOGY

To	Jean McQuade, The Arthritis Foundation of Western Australia, 17 Lemnos Street, Shenton Park WA 6009
From	Max Page, Executive Officer, Human Research Ethics Committee
Subject	Protocol Approval **HR 141/2002**
Date	1 August 2002
Copy	Dr Kathy Briffa, Physiotherapy

Office of Research and Development

Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL T.lerch@curtin.edu.au

On behalf of the Human Research Ethics Committee I am authorised to inform you that the project "A RANDOMISED CONTROLLED TRIAL OF AN OSTEOARTHRITIS SELF-MANAGEMENT PROGRAM" is approved.

Approval of this project is for a period of twelve months **29/Jul/2002** to **28/Jul/2003**.

When the project has finished or if at any time during the twelve months changes/amendments occur, the attached FORM B is to be completed and returned to Ms Tania Lerch, (Secretary, HREC) C/- Office of Research & Development as soon as possible. The approval number for your project is **HR 141/2002**. *Please quote this number in any future correspondence.*

Please find attached your protocol details together with the application form/cover sheet.

pp Maxwell Page
Executive Officer
Human Research Ethics Committee

J:\OR\HREC\REG99\HR 141/2002

Please Note:

If information about the authorisation of this project is required, the following standard statement is suggested for inclusion in the information to subjects section of the protocol.

This study has been approved by the Curtin University Human Research Ethics Committee. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784.

APPENDIX 4

Study 1 SF-36 Licence Agreement

LICENSE AGREEMENT

License Number: F2-052902-11204

This License Agreement is entered into, by, and between QualityMetric Incorporated (the "Licensor"), 640 George Washington Highway, Lincoln, RI 02865 and Arthritis Foundation of Western Australia (the "Licensee"), 17 Lemnos St., Shenton Park, Western Australia 6014, Australia.

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APPENDIX 5

Study 1 WOMAC Licence Agreement

-----Original Message-----
From: McGrath, Chesne [mailto:mcgrath@medicine.uq.edu.au]
Sent: Thu 2/20/2003 2:06 PM
To: Sophie Coleman
Subject: WOMAC(TM)

Email: sophiec@arthritiswa.org.au <mailto:sophiec@arthritiswa.org.au>

Dear Sophie,

Many thanks for your email of February 4th, 2003. Your project sounds very interesting. I would be pleased to provide the WOMACTM questionnaire for your study. I have attached a copy of the Academic User Agreement for your signature. I would be most grateful if you could fax back the completed document to me at 07 3851 1559. There is a nominal charge of AUD $110.00 (Inclusive of GST) to cover the costs of the WOMACTM User Guide, a copy of WOMACTM LK 3.1 for Australia, and the airmail and handling charge.
I trust that this nominal charge is acceptable.

Kind regards,

Nicholas Bellamy, MD, MSc, MBA, FRACP
Director of CONROD and
Chair of Rehabilitation Medicine
The University of Queensland

® WOMAC is a registered trade-mark
(CDN No. TMA 545,986)

"Progress through understanding"

Chesne McGrath
CONROD, Department of Medicine
The University of Queensland
Level 3, Mayne Medical School
Herston Road
Herston Qld 4006
* Telephone +61 7 3346 4783
Fax +61 7 3346 4603

APPENDIX 6

Study 2 Patient Information Sheet

A Randomised Trial of Two Osteoarthritis Self-Management Programs.
Investigators: Dr. Kathy Briffa, Sophie Coleman, Jean McQuade, Dr Charles Inderjeeth.

Introduction
The Arthritis Foundation of Western Australia and Curtin University are testing a new approach to the management of osteoarthritis. Osteoarthritis is the most common form of arthritis affecting about 10% of the Australian population. People with osteoarthritis report pain, stiffness, and a decline in quality of life as the disease progresses. Patient education, physical exercise and behavioral modification have been shown to have a positive effect on people with osteoarthritis and therefore we have formulated a program with these three components. We now wish to see how effective this program is for people with osteoarthritis and will compare it to an internationally recognized arthritis self-management program designed in the USA.

What does the study involve?
In this study we will compare our program with the arthritis program designed in the USA. This will involve recruiting people with osteoarthritis and then allocating them into either arthritis program. In order that we don't influence the results of the trial we are using special methods of allocating people to either program. This means that you will not be able to choose which program you are to attend and you will allocated to either program by a randomised draw.

Both programs consist of 8 two-hour sessions over a period of 2 months. The sessions will be held at the Arthritis Foundation, 17 Lemnos Street, Shenton Park. You will randomised and allocated to either a Tuesday morning program or a Thursday morning program. There will also be 2 follow up assessments at 6 and 12 months.

The Program
4. At the first, or baseline, session you will:

- Be asked to complete 3 physical tests:
  - Functional Knee Assessment Test in order to assess your knee function.
  - A balance test
  - A step test

- Be required to complete 4 questionnaires.
  - The WOMAC questionnaire asks questions specific to arthritis of the knee
  - SF36 questionnaire is a general health survey.
  - The VAS is a pain scale in which you rate the severity of your pain.
  - Self-efficacy questionnaire

The information that you give in the questionnaires will not identify you personally and it will be used to assess the effectiveness of the program.

You will also be required to:

- Be interviewed by a registered nurse who will record your current medications, relevant past medical history, date of birth, and photocopy your knee x-ray reports (if you have them). The information provided by you will be kept confidential and not used for any other purpose other than for the purpose of this study. If we are not sure that you have osteoarthritis of the knee we will need you to provide us with your doctor's contact details so that we may ask him/her to confirm your diagnosis.

5. Sessions 2 –6 inclusive
   Consist of 6 group education sessions (one session per week). Each session will run for 2.5 hours. These sessions cover the areas associated with osteoarthritis. At the first session you will be given a course book which you may use for the duration of the program, and throughout sessions 2-6 you will be given information sheets, which you may keep or return.

6. Session 8
   Occurs in the week immediately following the 6 education sessions. At this session the physical measurements and the questionnaires are repeated.

You should not enter this study if you plan to have knee surgery in the immediate future, if you have rheumatoid arthritis or other joint disease, or if you have physical impairments that preclude you from fulfilling the requirements of the program.

Benefits and Risks

The Arthritis Foundation of Western Australia has completed a study of this program and it will be compared to the US arthritis program. The results of this study show that those people who participated had less pain, and experienced improvements in their knee function and quality of life. There were no apparent risks associated with participation in this program or with the US program.

Withdrawal from the study

You may agree to participate in the study but change your mind later. You may withdraw from the study at any time without explanation and in this case your future treatment will not be affected.

Confidentiality and Security of information
Any information about you will be stored in a safe and secure way to prevent others from having access to it. The information provided by you will not be used for any other purpose other than for the purpose of this study. Results of the study may be published in a scientific journal without the use of your name or any other identifying information. The data collected will be kept for 7 years after which time it will be destroyed.

For more information about this study contact:

Sophie Coleman
Arthritis Foundation of Western Australia
17 Lemnos Street
Shenton Park, 6008
Telephone: 9388 2199

APPENDIX 7

Study 2 Consent Form

CONSENT TO PARTICIPATION IN A TRIAL OF TWO OSTEOARTHRITIS SELF-MANAGEMENT PROGRAMS

Investigators: Dr. Kathy Briffa, Sophie Coleman, Jean McQuade, Dr Charles Inderjeeth.

I have been given clear written information about this study. I have read and understood it. I have been given time to consider whether I want to take part.

I have been told about the possible advantages and risks of taking part in the study and I understand what I am being asked to do.

I understand that I will be allocated to either one of two arthritis self-management groups using the method outlined in the information brochure.

I understand that there will be follow-up assessments at 6 and 12 months.

I know that I do not have to take part in the study and that I can withdraw at any time during the study without affecting my future medical care.

I agree to take part in this research study and for the data obtained to be published provided my name or other identifying information is not used.

....

Name of Participant Participant Signature
Date

....

Investigator Investigators Signature
Date

Curtin University Human Research Ethics Committee has approved this research study.
If you have any ethical concerns regarding the study you can contact the secretary of the Curtin University Research Ethics Committee on Telephone No. 9266 2784

APPENDIX 8

Study 2 Ethics Approval

memorandum

To	A/Prof Kathy Briffa, Physiotherapy
From	A/Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval **HR 12/2006**
Date	01 February 2010
Copy	

Curtin University of Technology
Office of Research and Development
Human Research Ethics Committee
TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*Self-management for osteoarthritis of the knee: Does mode of delivery influence outcome?*". Your application was **approved** at Meeting 02/06 held 04 April 2006.

- The approval number for your project is **HR 12/2006.** *Please quote this number in any future correspondence.*
- Approval of this project is for a period of twelve months **09-03-2006** to **09-03-2007**. To renew this approval a completed Form B (attached) must be submitted before the expiry date **09-03-2007**.
- If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
- The following standard statement **must be** included in the information sheet to participants:
  This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 12/2006). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:
When the project has finished, or

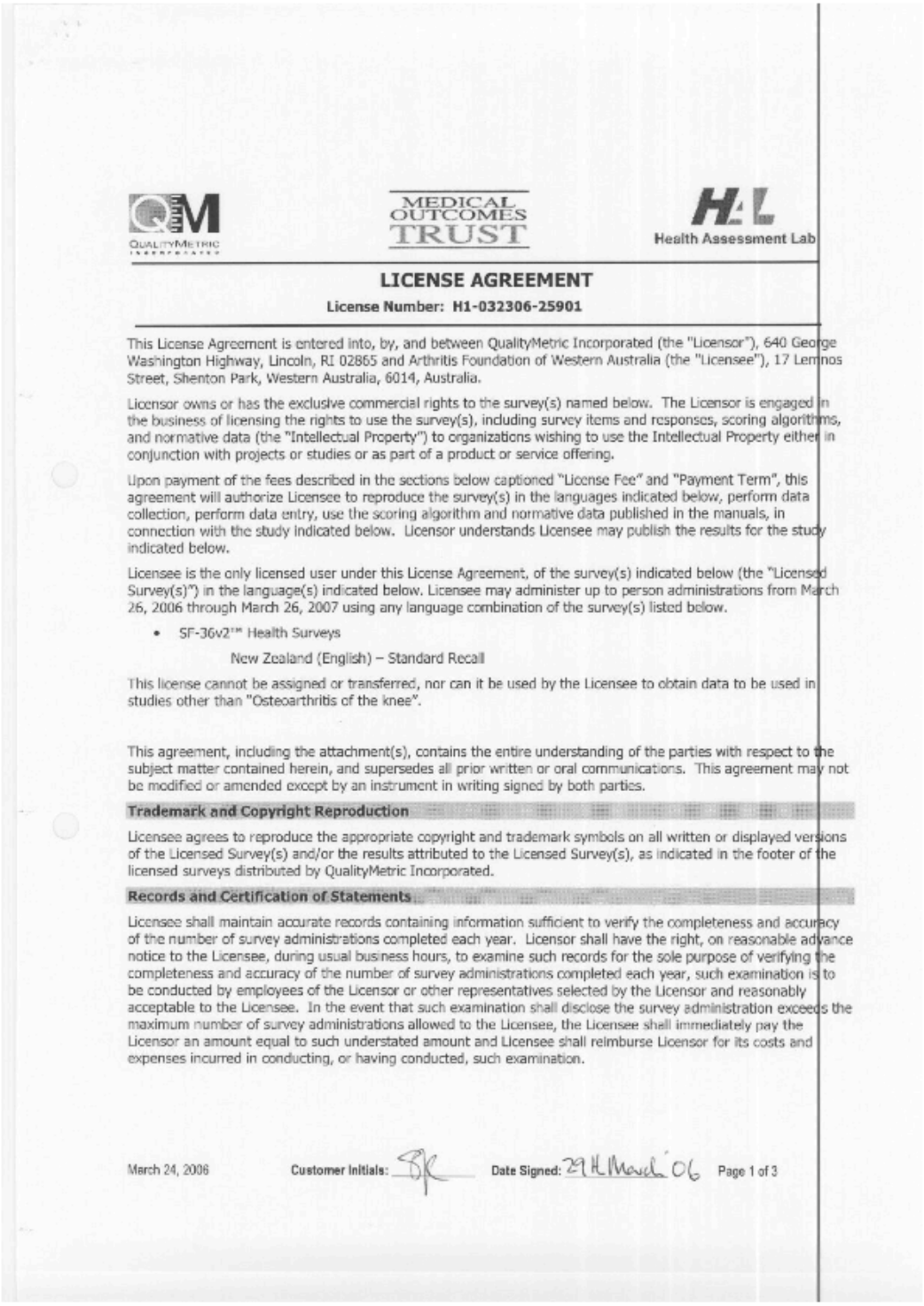
- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new application form (Form A), providing comprehensive details, must be submitted.

Regards,

A/Professor Stephan Millett
Chair Human Research Ethics Committee

APPENDIX 9

Study 2 SF-36 Licence Agreement



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March 24, 2006 Customer Initials: BK Date Signed: 29th March 06 Page 1 of 3

APPENDIX 10

Study 2 WOMAC Licence Agreement

Dear Sophie,

Thank you for your email of 4 September, 2008, and your completed WOMACTM Academic User Agreement dated 3 September, 2008, for your study of up to 150 patients, in a study entitled “A randomised controlled study to compare the effectiveness of the OAK and ASK self-management programs for people with OA knee”. From your email, I am not sure which publications you are seeking. By CII, do you mean Clinically Important Improvement?
I will send to you this week, a copy of the WOMACTM LK 3.1 English for Australia Index for use in your study of up to 150 patients in the aforementioned protocol. I will also send you 1 copy of WOMACTM User Guide IX. These will be sent to your designated address in Nedlands, WA. I would be most grateful if you could please confirm receipt of materials in due course. I am pleased to permit use of the WOMAC™ Index in the above protocol without charge on this occasion, and without setting a precedent for future use of the WOMAC™ Index.

Please note that the WOMACTM LK 3.1 English for Australia Index is a proprietary health status questionnaire, protected by copyright and trademark, and the physical form of the Index should not be published or placed in the public domain in paper, electronic or any other form, neither should the instrument be modified or provided to unlicensed users.

Please also note that this licensing Agreement relates to the study of up to 150 patients in the aforementioned protocol, and not to the study of additional patients in this protocol, or to use of the WOMACTM Index in other research protocols, clinical practice or other applications, without prior completion of a relevant User Agreement appropriate for that additional application, and remittance of applicable fees. Thank you for your interest in the WOMACTM Osteoarthritis Index.

Kind regards,

Nicholas Bellamy, MD, MSc, DSc, MBA, FRACP

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Prof. Nicholas Bellamy MD MSc DSc MBA FRCP (Glas, Edin, Canada), FACP, FAFRM, FRACP.
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APPENDIX 11

Quality Assurance Paper

Coleman, Briffa, et al. (2008b). “Effects of self-management, education and specific exercises, delivered by health professionals, in patients with osteoarthritis of the knee.” BMC Musculoskeletal Disorders 9:133.

BMC Musculoskeletal Disorders

BioMed Central

Research article

Open Access

Short and medium-term effects of an education self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals: a quality assurance study

Sophie Coleman*[1,2], Kathryn Briffa[2], Heather Conroy[1], Richard Prince[3], Graeme Carroll[4] and Jean McQuade[1]

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Email: Sophie Coleman* - sophiec@iinet.net.au; Kathryn Briffa - K.Briffa@exchange.curtin.edu.au; Heather Conroy - conroy@bigpond.net.au; Richard Prince - rlprince@cyllene.uwa.edu.au; Graeme Carroll - md@arthrocare.com.au; Jean McQuade - jeannm@arthritiswa.org.au

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Abstract

Background: Self-management (SM) programs are effective for some chronic conditions, however the evidence for arthritis SM is inconclusive. The aim of this case series project was to determine whether a newly developed specific self-management program for people with osteoarthritis of the knee (OAK), implemented by health professionals could achieve and maintain clinically meaningful improvements.

Methods: *Participants:* 79 participants enrolled; mean age 66, with established osteoarthritis of the knee. People with coexisting inflammatory joint disease or serious co-morbidities were excluded.

Intervention: 6-week disease (OA) and site (knee) specific self-management education program that included disease education, exercise advice, information on healthy lifestyle and relevant information within the constructs of self-management. This program was conducted in a community health care setting and was delivered by health professionals thereby utilising their knowledge and expertise.

Measurements: Pain, physical function and mental health scales were assessed at baseline, 8 weeks, 6 and 12 months using WOMAC and SF-36 questionnaires. Changes in pain during the 8-week intervention phase were monitored with VAS.

Results: Pain improved during the intervention phase: mean (95% CI) change 15 (8 to 22) mm. Improvements (0.3 to 0.5 standard deviation units) in indices of pain, mental health and physical functioning, assessed by SF-36 and WOMAC questionnaires were demonstrated from baseline to 12 months.

Conclusion: This disease and site-specific self-management education program improved health status of people with osteoarthritis of the knee in the short and medium term.

Background

With an ageing population, the prevalence of chronic disease is increasing. Osteoarthritis of the knee is a widespread chronic condition and one of the most common causes of musculoskeletal disability [1]. Complementary to conventional medical care, self-management interventions are considered to be beneficial in the management of people with chronic illness [2,3]. These interventions are designed to assist people to effectively manage their condition (between physicians visits), by teaching them how to cope with their symptoms, including the physical and psychological consequences of living with a chronic disease.

Approaches to self-management vary [4]. The majority of self-management interventions are led by health professionals (HP) in a group setting where all participants are affected by the same condition. Health professionals are a credible source of information for participants and have the knowledge to provide factual disease-specific education and respond to queries where required. When all members of a group have the same condition, all components of the intervention can be tailored to the specific needs of the group.

Notable exceptions to this approach are the Chronic Diseases and Arthritis Self-Management Programs (ASMP) developed at Stanford University [2,5]. These programs are also delivered in a group setting but are led by trained lay tutors. They have a more generic approach as they are catering for participants with a variety of different conditions in the one group. This approach is cheaper to deliver but cost-effectiveness is yet to be established [6,7]. Participants in the arthritis groups may include people with a variety of different rheumatic diseases.

The Arthritis Self-Management Program has been tested widely with the majority of studies conducted in the USA or UK. Many, but not all of these studies have found the program to be effective. Overall, Warsi et al (2004), in their systematic review of self-management interventions for various chronic diseases, found a trend towards a small benefit from arthritis programs, the majority being ASMP or ASMP derivatives, but the results were not significant and there was suggestion of publication bias [4].

In view of the high prevalence of OA knee in the community, we considered the development of a specific program to be justified. The goals of the program were to reduce pain, improve physical function and increase general well being. The program was designed to be delivered by HP's including physiotherapists, nurses and occupational therapists. It included disease specific education, including precise information on medications and analgesia as well as the importance of exercise and weight management. A social cognitive theory approach incorporating goal setting, problem solving and cognitive techniques was adopted to improve self-efficacy and facilitate long-term change in behaviour. Participants were encouraged to include exercise and effective pain management as well as specific information learned during the sessions in their weekly goal setting. This approach is a means of encouraging participants to incorporate specific education learned from week to week relevant to their disease [8,9]. The HP leaders can provide support and specific feedback for any problems that were encountered.

The newly developed OAK program was implemented as a clinical service of the Arthritis Foundation of Western Australia (WA). We report here the progress of participants during the implementation phase and 12 month follow up. The aim was to determine whether participants had experienced improvements in quality of life, pain, stiffness, and physical function, and whether these improvements would be maintained for 12 months.

Methods

This case series quality assurance project was conducted within the clinical services provided at Arthritis Western Australia. Public awareness of the programs offered by Arthritis WA is often generated via General Practitioner referral or suggestion from friends or family. Programs and services are also advertised in community newspapers; quarterly Arthritis WA magazines; and local radio stations, often linked to health or scientific articles.

This quality assurance project was given Institutional approval by the Board of Arthritis WA and the OA Knee Advisory Committee and complies with National Health and Medical Research Council (Australia) criteria for quality assurance programs [10].

Participants

People with OA knee enquiring consecutively to Arthritis WA about access to appropriate services were invited to participate in the new disease specific self-management program. Those who were not interested in the OAK program, did not meet the selection criteria, or were not confident they would be able to participate fully were encouraged to utilize other appropriate services of Arthritis WA.

Only those with a diagnosis of OA of the knee were enrolled. It was a requirement that the diagnosis was confirmed by the participant's medical practitioner. Diagnostic criteria were at the discretion of the doctor. Disease severity was not a selection criterion. Unilateral total knee replacement did not preclude enrolment. Other criteria for ineligibility was age greater than 85 years; inability to walk 300 meters; inflammatory joint disease including

rheumatoid arthritis; major concurrent illness such as cancer; bilateral knee replacement; knee surgery scheduled within 6 months of commencing the program; or physical impairments that precluded fulfilling the requirements of the program. Those people were referred to other available services.

This project was consistent with the National Health and Medical Research of Australia definition for a quality assurance project [11]. The OAK program and the associated clinical assessments were clearly described to all volunteers who had the opportunity to have all questions answered and provided verbal consent to participate.

Intervention

Groups of 8–10 participants attended 6 education sessions (one 2.5-hour session per week). Participants were provided with written material relevant to the information component discussed each week. The program used a holistic approach, including a range of aspects of care such as:

- Pain management strategies
- Exercise advice
- Joint protection
- Medication/analgesia
- Balance and falls prevention
- Coping with negative emotions
- Fatigue
- Self-management skills (goal setting, problem solving, cognitive techniques)

The fidelity of the OAK program was maintained by the use of a facilitator's manual with modules for program delivery each week. The program was delivered by 2 nurses and assessments were performed by 3 physiotherapists who had no contact with the participants other than during the assessment sessions. Participants were assessed by the same physiotherapist whenever possible to ensure consistency. The assessors did not participate in the facilitation of the program. It was a requirement that health professionals who delivered the program meet minimum musculoskeletal knowledge requirements.

Attendance was recorded at each of the 6 intervention sessions and at each assessment time-point.

Response to Intervention

Participants were assessed at baseline, immediately post-intervention at 8 weeks, and at 6 and 12 months after the program. In addition, pain was assessed on a week-to-week basis during the first 8 weeks using a VAS.

Assessments included

Health status was assessed using both a disease specific and a generic index as follows:

- The disease specific WOMAC Osteoarthritis Index (WOMAC LK3.0) assesses pain, stiffness and physical function in people with OA of the hip or knee [12]. Validity and reliability of the WOMAC pain, physical function and stiffness subscales are well established and the questionnaire is sufficiently sensitive to detect changes in health status in response to intervention [12].

- The generic Medical Outcomes Study Short Form 36 Version 1 questionnaire (SF-36). The SF-36 was designed to provide a profile of scores that would be useful in understanding the health burden in chronic diseases and the effect of treatment on general health status. It includes 8 component sub-scales that correspond to aspects of physical and mental health and well being [13]. Adequate reliability for between group comparisons has been demonstrated in numerous studies and an English version of the questionnaire has been developed and validated specifically for use in Australia [14]. For people with OA, an improvement of 5 points on the physical component score of the SF-36 is considered to be clinically significant [15].

Pain was assessed using pain scales included in the WOMAC and SF-36 indices. During the intervention period, pain was monitored on a week-to-week basis (Figure 1) using a 100 mm VAS. The left hand anchor was "No Pain", and the right hand anchor "Worst Pain". The VAS is well established in clinical practice for measuring pain levels post-surgery, following drug therapy and other interventions in arthritis populations [16]. A reduction of 30% or 2 points in VAS is considered to represent a clinically important difference [17,18].

Active range of motion of knee flexion and extension were measured using a long armed goniometer [19]. The reliability and validity of the goniometer is well established for measurement of active knee flexion and extension [19,20].

Balance was assessed using a timed single leg balance test. This simple test assesses the length of time, to a maximum of 10 seconds, a person can stand on one leg. It is a good predictor of falls in the elderly [21] and is reliable and valid [22].

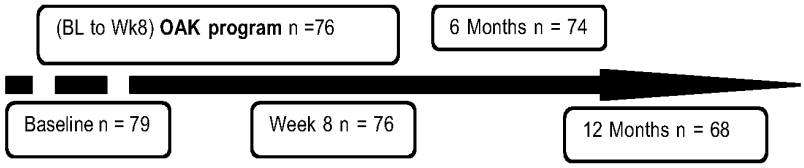

Figure 1
Flow chart time-points with number of participants attending. Baseline to week 8 (intervention), 6 months and 12 months (follow-up assessments)

Statistical Analysis

Data were analysed using SPSS v16 for Macintosh. One-way (repeated measures) analysis of variance with *time* (baseline, 8 weeks, 6 months and 12 months) as the independent variable was used to assess changes in the variables of interest. Where the ANOVA was significant pairwise differences between baseline and 12 months were compared using paired t-tests and mean change and 95% confidence interval for were calculated. The effect size for the pair wise comparison was calculated using Cohen's *d* (the difference between the means: M_1 - M_2 divided by the standard deviation). Improvement is represented as a positive difference: small, $d = 0.2$; medium $d = 0.5$; large $d = 0.8$ [23] allowing the comparison of outcomes across the intervention. Separate models were constructed for each outcome variable. Normal distribution and homogeneity of the variance were confirmed prior to further analysis. Statistical significance was inferred at a 2-tailed $p < 0.05$.

Results

141 people expressed interest in the OAK program. Recruitment for the project was discontinued when 8 groups of eligible participants (19 men, 60 women, mean (SD) age 66 (9) had enrolled in the program. Of these, 68 participants completed the program and returned for all the follow-up assessments to 12 months. Those who were absent or likely to be absent for more than 2 of the 6 sessions were deferred to the next group (Table 1). All the participants included in the analyses attended at least 4 of the 6 self-management sessions with the average attendance being 5.8 sessions. The reasons cited for withdrawal were overseas relocation and work, family, and time commitments. Close to 90% of participants had other co-existing disease (Table 1).

Socio-economic status was estimated according to residential address postcodes using a method developed by the Australian Bureau of Statistics – "The Index of Relative Socio-Economic Disadvantage" [24]. This index provides a weighted value that includes variables that reflect or measure disadvantage. These variables include: low-income, low educational attainment, high unemployment, and low skilled occupations. A low index value represents disadvantage and a high index value represents advantage in an area. Participants in the OAK program were over represented in the highest group (Table 1).

Table 1: Characteristics of participants enrolled in OAK program

Gender (F:M)	**60:19**
Age: mean (SD) years	**66 (9)**
Socio-Economic Index by Post Code [24]	**Number (%)**
Index measured in quintile ranges	
Top 25%	59 (74.6)
50–75%	7 (8.8)
25–50%	7 (8.8)
10–25%	3 (3.8)
Bottom 10%	3 (3.8)
Coexisting disease	**n (%)***
Cardiovascular, n (%)	48 (45)
Mental Health, n (%)	9 (11)
Gastrointestinal, n (%)	27 (30)
Endocrine, n (%)	15 (18)
Musculoskeletal, n (%)	16 (20)
Osteoporosis, n (%)	14 (18)
Multiple co-morbidities, n (%)	51 (64.5)
Other, n (%)	31 (61)
No co-morbidities, n (%)	12 (15)

*Percentage adds > 100 as some participants have more than one coexisting disease

Table 3: SF-36 scores at baseline, 8 weeks, 6 months and 12 months

SF-36 (0 to 100)	**BL**	**8 wks**	**6 mths**	**12 mths**	**F (df)**	***p*-value**	**Change at 12 mths Mean (95% CI)**	**Effect size (d)**
Physical Function	47.36 (2.49)	52.00 (2.62)	56.13 (2.62)	55.66 (3.13)	$5.47_{(3,201)}$	< 0.001	7.73 (2.70 to 12.70)	0.3
Role Physical	29.77 (4.54)	41.54 (4.87)	43.01 (4.99)	46.69 (5.23)	$4.48_{(3,201)}$	0.004	16.91 (7.20 to 26.50)	0.4
Bodily Pain	35.50 (1.85)	40.39 (2.06)	41.52 (2.52)	43.64 (2.49)	$3.49_{(3,201)}$	0.017	8.14 (3.03 to 13.20)	0.5
General Health	63.72 (2.58)	67.05 (2.25)	69.13 (2.57)	69.79 (2.50)	$3.42_{(3,201)}$	0.018	6.07 (1.50 to 10.50)	0.3
Vitality	50.41 (2.73)	56.38 (2.10)	57.30 (2.41)	60.73 (2.58)	$7.64_{(3,201)}$	< 0.001	10.30 (5.20 to 15.30)	0.4
Social Function	69.64 (3.04)	78.67 (2.46)	76.72 (2.81)	79.98 (2.72)	$5.16_{(3,201)}$	0.002	10.30 (4.80 to 15.70)	0.4
Role Emotional	53.97 (5.31)	66.14 (4.81)	71.05 (4.98)	73.01 (4.80)	$5.27_{(3,201)}$	0.002	19.04 (9.10 to 28.90)	0.4
Mental Health	71.02 (2.25)	77.11 (1.70)	79.00 (1.90)	78.73 (2.11)	$9.34_{(3,201)}$	< 0.001	7.70 (3.60 to 11.70)	0.4

Values are mean (SE). Higher scores indicate improvement; F-values and p-values are for repeated measures ANOVA. Change at 12 months values are mean (95% CI). Effect size is for pair wise comparison between baseline and 12 month scores.

As participants increased their exercise level over the 8-week intervention period, most had a reduction of pain, improved wellbeing and feelings of accomplishment that motivated them to continue. What was previously negative reinforcement (pain) changed to become positive reinforcement (less pain and improved well being) [28].

Education in the correct use of medication and analgesia is linked to the point above. Fear of pain is often a greater limiter than pain itself – hence the fear of developing pain will inhibit people from attempting certain activities. Most people attending this QA program did not take analgesia to adequately control their pain. When participants felt confident that they could control their pain, they became more confident that aspect of their OA was manageable (and would exercise more, for example) [4]. Cognitive pain management was also part of the program syllabus and complemented pharmacological pain management.

Developing problem solving skills was encouraged. HP's skilled in musculoskeletal conditions offered advice or alternatives when hurdles were encountered so that participants achieved solutions rather than giving up, thereby improving SMART goal success and consequently improving self-efficacy [26]. Subsequent problems encountered were more likely to be problem solved rather than met with a defeatist attitude [6].

Using a self-management format to embrace HP skills, expertise and knowledge to deliver education in a format that participants could relate to in everyday life was hoped to improve self-efficacy in areas across the OA spectrum. It was thought that this would promote healthy life style and behaviour changes that would improve pain, physical function and quality of life.

Pain

In this study pain was measured in a number of ways, all demonstrating an improvement. A number of aspects of the self-management intervention may have contributed to the reduced pain levels reported by participants. Both aerobic and resistance exercise in a home-based exercise program have been shown to significantly reduce knee pain in-patients with OA [29,30]. An important component of the OAK intervention is discussion on the formulation of a comprehensive home exercise program that incorporates strengthening, endurance, balance and flexibility components. Participants were not taken into a gym or given individual personal training; however they were encouraged to pursue that option independently.

The exercise component was not controlled and participants freely chose the type of exercise/s and the degree to which they would comply. By providing a number of exercise alternatives, it was hoped that exercise routines would become habitual by the end of the 6-week program. In accordance with self-management principles, participants were motivated to use their "library" of exercise choices when planning their weekly goals. The use of goal setting with participants promoted good adherence to the exercise program, as reported each week, but data regarding adherence were not collected for this study.

As well as exercise instruction and cognitive therapies, medication usage and therapeutic dosing principles in particular for analgesia were taught to encourage medication compliance and effective pain management. The average age of participants was 66 years and most had several co-morbidities requiring medication (Table 1). Many participants had an aversion to medications and delayed taking analgesia until their pain was acute and therefore more difficult to control. Pain management guidelines were discussed with the aim of determining patterns of pain. For example short term "around the clock" analgesia dosing for acute pain, or "as needed" analgesia for intermittent pain.

It is likely that the OAK intervention has facilitated better pain-coping skills that are important predictors of disabil-

ity associated with OA. Previous studies have reported that catastrophizing and negative self-statements are associated with increased knee pain [31]. In the OAK intervention, participants were taught strategies for cognitive symptom management such as distraction, guided imagery, relaxation and thought challenging techniques that are considered to be important additional measures of pain management in people with OA [30,32].

Health Status

Participants reported considerable improvements in physical function. Like pain, functional improvements were reflected by changes in a number of the parameters measured. It is generally accepted that the WOMAC questionnaire has greater specificity and consequently better responsiveness for people with OA [33], nonetheless, the SF-36 also reflected these changes.

Interpreting these results requires some understanding of the value patients place on improvements of this magnitude. Establishing this can be difficult. A number of methods, each with strengths and limitations, have been used but findings are not entirely consistent. Improvements of 9% to 10% in WOMAC scores in response to rofecoxib or ibuprofen were perceptible to patients with OA knee [34] when anchored against a patient global assessment of response to therapy. Changes observed in our study were generally more than twice this magnitude. On the other hand the 21.6% improvement in WOMAC function was somewhat less than 26%, the minimal level suggested by Tubach et al [35] as clinically important.

Expressed as effect sizes in standard deviation units the improvements in the WOMAC pain and SF-36 bodily pain domains would be considered moderate [23]. The consistency of this effect between different outcome tools supports the validity of the change. Effect sizes for the WOMAC functional domain and for the SF-36 mental health domains were slightly lower at 0.4. Notably these effect sizes are larger or comparable to the pooled effect sizes for general pain from systematic reviews of NSAID therapy [36] and aerobic walking [37] (0.33 and 0.52 respectively), although larger effects are often observed in uncontrolled studies. Further context for interpretation of the improvements we observed in quality of life measured by the SF-36 may be provided by considering the average decline of 2.1 points over 12 months reported in people with OA in this age group [15].

Limitations

The subjects who attended this quality assurance program were typical of those who attend self-management programs run by Arthritis WA. Over representation in the highest socio-economic group (Table 1) may affect the reproducibility of this program, however, the demographics of the area this program was conducted in are consistent with this attendance statistic. These results should be interpreted with caution as this limits the generalization to other socio-economic groups. Testing the OAK program with other socio-economic groups was outside the limitations of this QA program.

It is important to note that no control period or control group were available for comparison. Consequently, the clinical improvements observed in this cohort should be interpreted with caution. Despite this, improvements in response to this disease specific self-management program delivered by health professionals are encouraging and have interest. We therefore propose to further evaluate the benefits of this program using a more rigorous study design.

Conclusion

Improvements in pain, health status and physical function were observed in response to our SM education program specifically designed for people with OA knee, delivered by health professionals. Health professionals providing the program enabled inclusion of disease specific content, not found in other arthritis SM programs, to be incorporated in the OAK program. The long-term gains demonstrated in OAK are not reflected in other arthritis SM programs. Furthermore rigorous investigation of the benefits of this approach to treatment is warranted.

Abbreviations

SM: self-management; OAK: osteoarthritis of the knee; OA: osteoarthritis; HP: health professional; QA: quality assurance; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; VAS: visual analogue scale; CI: confidence interval; ASMP: Arthritis Self-Management Program; SF-36: Medical Outcomes Short Form 36 Questionnaire; SMART: specific, measurable, achievable, realistic, timely; NSAID: non-steroidal antiinflammatory drug

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

SC, RP, GC, JM contributed to study design. SC and HC were responsible for the acquisition of data and SC the data-entry. All authors contributed to analysis and interpretation of the data. KB and SC contributed to manuscript preparation. All authors have approved the final version of the manuscript.

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APPENDIX 12

Self-Efficacy Questionnaire

For each of the following questions, please circle the number that corresponds to how certain you are that you can do the following tasks regularly at the present time.

1. How certain are you that you can decrease your pain quite a bit?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

2. How certain are you that you can keep your arthritis pain from interfering with your sleep?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

3. How certain are you that you can keep your arthritis pain from interfering with the things you want to do?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

4. How certain are you that you can regulate your activity so as to be active without aggravating your arthritis?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

5. How certain are you that you can keep the fatigue caused by your arthritis from interfering with the things you want to do?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

6. How certain are you that you can do something to help yourself feel better if you are feeling blue?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

7. As compared with other people with arthritis like yours, how certain are you that you can manage pain during your daily activities?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain

8. How certain are you that you can deal with the frustration of arthritis?

Very uncertain	1	2	3	4	5	6	7	8	9	10	Very certain