A comparison of the Stanford model chronic disease self management program with pulmonary rehabilitation on health outcomes for people with chronic obstructive pulmonary disease in the northern and western suburbs of Melbourne.

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Statement of Sources

This thesis contains no material published elsewhere or, extracted in whole or in part from a thesis by which I have qualified for or, been awarded another degree or diploma.

No other person's work has been used without due acknowledgement in the main text of the thesis with the exception of the medical chart review to audit the documented planned and unplanned health resource use by the study participants described in Chapters Five and Six. This data collection was undertaken by Victoria Lawlor RN and entered in to an electronic Excel database I had created. All aspects of the dataset from Hospital B (the Control group), as reported in the thesis is solely due to the work of Katherine M^{C}Cann.

This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

All research procedures reported in the thesis received the approval of the relevant Ethics/Safety committees where required.

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Abstract

Previous researchers have identified that participation in a pulmonary rehabilitation program improves health outcomes yet, continuation in a weekly maintenance program yielded mixed results. Self-management programs have had reported use in chronic obstructive pulmonary disease (COPD). A meta-analysis has identified that no self-management program had evaluated the effect of this type of intervention on the functional status of the participant with COPD. Reduced functional status is well reported as an indicator of disease progression in COPD. Adjuvant therapies for people with COPD need to demonstrate an effect in this domain. The Stanford model chronic disease self-management program (CDSMP) had been reported as a program that may optimise the health of people with chronic health conditions. However, its utility has not been formally evaluated for people with COPD. There have not been any reports of a comparison of the Stanford model CDSMP with pulmonary rehabilitation via a randomised controlled study in COPD. Aim: To compare and evaluate the health outcomes from participation in nurse led wellness-promoting interventions conducted in the ambulatory care setting of a metropolitan hospital. Participants were randomised to either a six-week behavioural intervention: the Stanford model CDSMP or, a six-week pulmonary rehabilitation program and results compared to usual care (a historical control group). The efficacy of the interventions was measured at week seven and repeated at week 26 and 52. Following the week seven evaluation, the pulmonary rehabilitation program participants were re-randomised to usual care or, weekly maintenance pulmonary rehabilitation for 18 weeks and, followed up until the study completion at week 52. Little is reported about the costs of care for people with COPD in Australia. This study prospectively evaluated the costs of the interventions and health resource for the 52 weeks and undertook a cost utility analysis. Methods: Walking tests (The Incremental Shuttle Walking Test) and questionnaires asking participants about their health related quality of life, mood status, dyspnoea and self efficacy were assessed prior to randomisation to either six week intervention and repeated at weeks 7, 26 and 52. The implementation of these adjuvant therapies enabled all costs associated with

the interventions to be prospectively examined and compared. Results: During the two years of recruitment 252 people (54% males) with a mean age 71 years (SD 11, range 39-93 years) were referred to the study. Student's t-tests identified that there were no statistically significant differences (P=0.16) between all those referred by age and gender as compared to all those admitted to Hospital A with an exacerbation of COPD. Ninety-seven people (51% male) with a mean age of 68 years (SD 9, range 39-87 years) agreed to participate in the study. Follow up in the study continued for 12 months following enrolment with only a modest level of attrition by week seven (3%) and week 52 (25%). Following the six-week interventions, both the pulmonary rehabilitation and CDSMP groups recorded statistically significant increases in functional capacity, self-efficacy and health related quality of life. Functional performance was additionally evaluated in the intervention arms with participants wearing pedometers for the six-week period of the interventions. There were no statistically significant differences between steps per week (P=0.15) and kilometres per week (P=0.17) walked between these two groups in functional performance. The Spearman rho statistic identified no statistically significant relationship between functional performance and the severity of COPD (r_s (33) = 0.19, P = 0.26). No significant correlation between functional capacity and functional performance was identified (r_s (32) = 0.19, P = 0.29). This suggests that other factors contribute to daily functional performance. The largest cost of care for people with COPD has been reported to be unplanned admissions due to an exacerbation of COPD. In this study there were no statistically significant differences between the three intervention groups in the prospective measurement of ambulatory care visits, Emergency Department presentations and admissions to hospital. The calculation of costs illuminated the costs of care in COPD are greater than the population norm. In addition, maintenance pulmonary rehabilitation generated a greater quality adjusted life year (QALY) than a six-week program. Despite the strength of the participants preferences (as measured by the QALY) for maintenance PRP, there were no significant differences in use of hospital resources throughout the study period by the three intervention groups, which suggests some degree of equivalence.

List of publications and presentations

The following have been presented &/or published at the time of thesis submission:

Peer reviewed publications

1) Murphy MC, Saunders JE, Campbell M, Jackson B, Berlowitz DJ. 2003 The process of implementing the Stanford Model Chronic Disease Self Management Program: The Northern Hospital experience. *Australian Journal of Primary Health* (9): 127-131.

2) Harvey PA, Murphy MC, Doremann E, Berlowitz DJ, Jackson B. 2005 Implementing evidence based guidelines: inpatient management of COPD. *Internal Medicine Journal* (35): 151-155.

3) Murphy MC, Campbell M, Saunders JE, Berlowitz DJ. 2005. The process of implementing a nurse co-ordinated multi disciplinary pulmonary rehabilitation program in Melbourne. *Contemporary Nurse* Volume 19:(1-2): 222-231

4) Murphy MC, Saunders JE, Campbell M.2007 Mechanisms and Classifications of COPD: a literature review *Contemporary Nurse* Volume 25:(1): 4-12

Published Abstracts

i) Thoracic Society of Australia & New Zealand (TSANZ) Annual Scientific Meeting March 20-24 2004 "A randomized controlled trial of pulmonary rehabilitation, weekly exercise and the better health self-management program".
Murphy MC, Campbell M, Saunders JE, Jackson B, Rangan NF, Zimmermann F, Berlowitz DJ. *Respirology* 2004 March (9)s:A48

ii) Thoracic Society of Australia & New Zealand (TSANZ) Annual Scientific Meeting March 19-23 2005 A randomized trial to compare pulmonary rehabilitation and the Stanford model self management program in COPD with 12 month follow up
Murphy MC, Berlowitz DJ, Campbell M, Saunders JE, Jackson B. *Respirology* 2005 March (10)s: A61

iii) American Thoracic Society (ATS) Annual Scientific Meeting May 20-25 2005. A randomised trial to compare the outcomes of a pulmonary rehabilitation program, weekly maintenance and the Stanford Model chronic disease self-management program in COPD.
Murphy MC, Campbell M, Saunders JE, Jackson B.

Oral presentations

iv) Australian Government Department of Health and Aging Dimensions in Health Care Conference: Sydney October 10-13 2004
" A flexible questionnaire management system"
Kenyon DR, Rustem Y, Murphy MC, Berlowitz DJ, Wyatt M, Jackson B.
www.health.gov.au/casemix/conf.htm

v) Ambulatory Care Australia Conference: Disease Management & Enabling Technologies in Ambulatory Care: Melbourne September 9-10 2004.
"A comparison of peer led and clinician led chronic disease self management programs"
Murphy MC, Campbell M, Saunders JE, Berlowitz DJ, Jackson B.
www.health.vic.gov.au/aca/

vi) Australian Government Department of Health and Aging National Chronic Condition Self-Management Conference: Melbourne 12-14 November 2003
"An investigation of Health Outcomes in the COPD population: The Northern Hospital's experience"
Murphy MC, Jackson B, Campbell M, Saunders J, Berlowitz D
http://www.chronicdisease.health.gov.au/sharing.htm

Poster presentations

vii) Royal Australian College of Physicians (RACP) & the Thoracic Society of Australia & New Zealand (TSANZ) Joint Annual Scientific Meeting: Christchurch New Zealand August 3-6 2004 *"Improving Health Outcomes in a COPD population: a randomized trial to compare the outcomes of a participation in a Pulmonary Rehabilitation Program (PRP) and the Stanford Model Chronic Disease Self Management Program (CDSMP)".*
Murphy MC, Campbell M, Saunders JE, Berlowitz DJ, Jackson B.

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List of Abbreviations

AIHW …….Australian Institute of Health & Welfare

ANADA……...The Australian Nursing Alternative Documentation Assessment Tool

ATS …….American Thoracic Society

BMI …….Body Mass Index

BTPS …….Body temperature, ambient pressure, saturated with water vapour

BTS …….British Thoracic Society

CDSMP……Chronic Disease Self Management Program

CEA …….Cost effectiveness analysis

CONSORT……..Consolidated standards for reporting of trials

COPD …….Chronic Obstructive Pulmonary Disease

CR……Cardiac rehabilitation

CRDQ……..Chronic respiratory disease questionnaire

CUA …….Cost utility analysis

Df …….Degrees of freedom

ED ……. ….Emergency Department

η …….Eta

E/O …….Exacerbation of

ERS …….European Respiratory Society

FEV1……Forced Expiratory Volume in one second

FVC …….Forced Vital Capacity

GSES …….General Self Efficacy Scale

GOLD …….Global initiative for COPD

HRQoL……Health related quality of life

ICER …….Incremental cost effectiveness ratio

INO_2 …….Intranasal oxygen therapy

IQR …….Interquartile range

ISWT …….Incremental shuttle walking test

LOS …….Length of stay

LVRS……...Lung volume reduction surgery

MCID …….Minimal clinically important difference

M …….Mean

MR …….Mortality rate

MRC……Medical Research Council

MS …….Mean square

PRP …….Pulmonary rehabilitation program

PRP+m…….Pulmonary rehabilitation maintenance program

QALY …….Quality adjusted life year

RFT …….Respiratory Function Test

RPE …….Rate of perceived exertion

SaO_2 …….Arterial oxygen saturation

SD …….Standard deviation

SET …….Self Efficacy Theory

SGRQ …….St George Respiratory Questionnaire

The AQoL …….The Assessment of Quality of Life

The HAD…….The Hospital Anxiety and Depression scale

Σ …….Total

TLCO …….Carbon monoxide pulmonary diffusing capacity

TNF-α ……Tumour necrosis factor – alpha

TPB …….Theory of Planned Behaviour

TRA …….Theory of Reasoned Action

TSANZ……Thoracic Society of Australia & New Zealand

TTM …….Trans Theoretical Model

USA …….United States of America

Chapter One Introduction

This chapter provides an outline of the study. It defines the chronic respiratory condition of interest, background to the project and offers a rationale and outline of the interventions to be evaluated.

Quality of life, rather than simply measures of life expectancy, is increasingly regarded as a valid determinant of the success of any health intervention. Provision of care that facilitates an improvement in health related quality of life is now an expectation; however, this needs to be coupled with outcomes that are economically sustainable. This study will examine some of the challenges offered by these twin expectations.

Consumers, health care professionals and politicians are increasingly expecting more from their health services and at a reasonable cost. Strategies that improve health status should lead to cost savings in the management of chronic conditions (Wagner, 1998). However, an effective health care model should enable cost savings to result from the implementation of valid interventions that reduce the need for readmissions due to an exacerbation of the condition.

Optimal evaluation of health care interventions requires an examination of the long-term effects of physiological, psychological and economic health outcomes. Health care interventions increasingly aim, and indeed are expected to demonstrate effectiveness across all of these domains. A scientific approach and measurable outcomes are expected in the evaluation of health interventions. Experimental designs that are replicable and control for bias are favoured (Beanland, Schneider, LoBiondo-Wood, & Haber, 2000).

This project sought to implement and evaluate the effect of nurse led interventions on participants with a chronic health condition. A chronic health condition may be defined as an illness where "no cure is possible and clinical decisions hold the potential only for symptom reduction or containment of deterioration" (Watt, 2000, p.7). A chronic illness may take a number of

forms, yet the principles to successfully live with a chronic illness are common to all chronic conditions. Symptom management, reducing anxiety and encouragement to participate in physical activities, are noted as categories addressed in best practice programs of chronic disease management (Clark, Bailey, & Rand, 1998). Self care management strategies, collaboration between the patient and the health service; formation of action plans responsive to changes in health outcomes; and follow up over the longer term have been identified as traits that define effective chronic disease management rather than a reactive approach to a change in health status (Von Korff, Glascow, & Sharpe, 2002). Whilst there are a great number of illnesses that may be labelled a chronic condition, this study examines one: Chronic Obstructive Pulmonary Disease (COPD) and, evaluates the potential benefit that pulmonary rehabilitation and the Stanford model chronic disease self-management program may confer in this population group.

1.1 Definition of COPD

In 2003, the Australian and New Zealand guidelines for the management of COPD defined the condition as a chronic and progressive illness that may cause serious co-morbidities and exacerbations which induce major care burdens on the healthcare system. COPD results in airway narrowing, loss of elastic recoil, and, altered respiratory architecture. The clinical features of COPD include dyspnoea, chest tightness and, in the later stages, cor pulmonale and hypercapnia (McKenzie, Frith, Burdon, & Town, 2003).

In the tenth edition of the National Centre for Classification of Diseases – Australian Modification (ICD10 – AM) manual, the relevant chronic respiratory diseases are listed as follows:

"J40 Bronchitis,
J41 Simple and mucopurulent chronic bronchitis,
J42 Unspecified chronic bronchitis,
J43 Emphysema,
J44 Other Chronic Obstructive Pulmonary Disease,
J45 Asthma,
J60 Coal workers pneumoconiosis,
J68.4 Chronic respiratory conditions due to chemicals, gases, fumes & vapours"
(National Centre for Classification in Health, 1998, pp196-198).

COPD is a clinical condition defined by fixed airflow limitation. This condition is not fully reversible although the use of bronchodilator medication may result in some degree of airway reversibility. This partial airway responsiveness to therapy results in a clinical overlap between COPD, asthma and chronic bronchitis. A non-proportional Venn diagram (see Figure 1.1) to depict this overlap was originally utilised by the American Thoracic Society (ATS) (ATS, 1995b), and in more recent times in the Australian and New Zealand expert guidelines (McKenzie et al., 2003). In 1991, the ATS reported that there was little consensus on the degree of airway reversibility considered more consistent with asthma than emphysema. The ATS and British Thoracic Society (BTS) had reported that a reversibility in the order of 12-15% percent from baseline should be considered a significant bronchodilator response (ATS, 1991; BTS, 1997). Today, this lack of consensus remains in the literature as evidenced by the American, British and European Thoracic Society guidelines (ATS, 1995b; BTS, 1997; Siafakas et al., 1995). For the purposes of this project, all participants who reported greater than 15% reversibility from their baseline measurement were excluded from this COPD study, as this is the most commonly used criterion in Australia and New Zealand to define COPD (McKenzie et al., 2003; Reid et al., 2003).

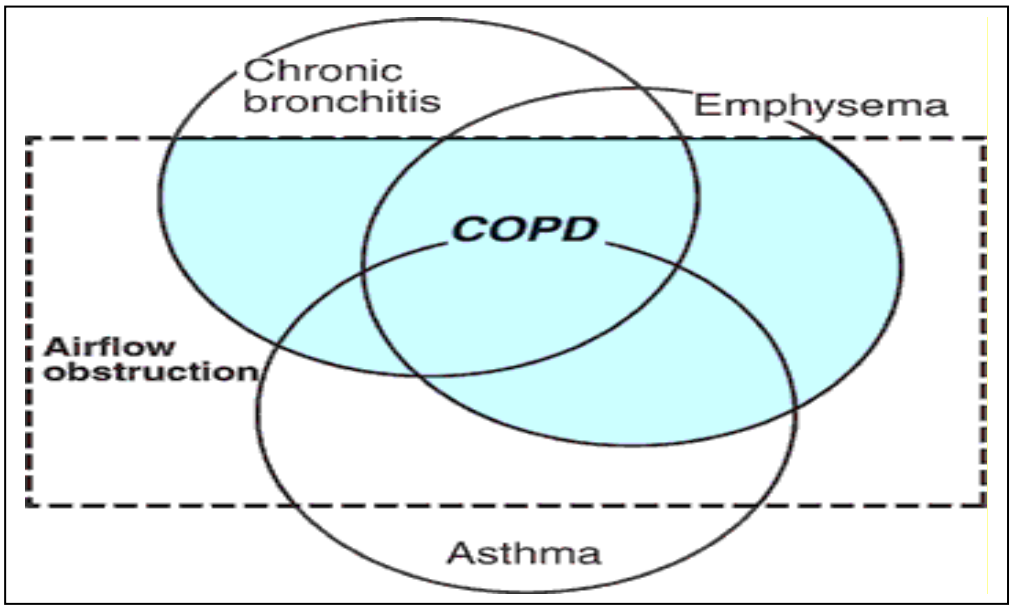


Figure 1.1: Non proportional Venn diagram of the overlap between asthma, emphysema and bronchitis: (McKenzie et al., 2003 ,p.S10).

1.2 Background

In 1990, COPD was ranked twelfth with respect to the global burden of disease. It has been projected COPD will be ranked fifth by 2020 (Murray & Lopez, 2002). Advanced age and improved diagnosis of the condition, coupled with the disease burden from tobacco use, have all contributed to COPD's elevation in ranking within the Global Burden of Disease figures. The global prevalence of COPD cases has been estimated as 11.6/1000 for men, and 8.77/1000 for women (WHO, 2006). In Australia, the impact of COPD may be viewed from a number of perspectives such as national and regional. A review of this condition at each of these tiers will illustrate its prevalence and its impact on health outcomes.

1.2.1 The National perspective

Nationally, COPD was ranked as the third most common chronic condition behind heart disease and stroke (AIHW, 2002b) with nearly 10% of our adult population over the age of 45 years affected (Clinical Evaluation and Health Service Evaluation Unit, 1999; Crockett, Cranston, & Moss, 2002). It was the fourth most common cause of death for Australians, behind heart disease, stroke and all types of cancer (ABS, 2002, 2003; AIHW, 2005b; Clinical Evaluation and Health Service Evaluation Unit, 1999; Crockett et al., 2002). It had been reported that the average age for the onset of COPD in Australia is 59.7 years for men and 63.3 years for women. The mean duration of living with COPD for Australians is 17 years (AIHW, 2002b). The national prevalence of COPD has been reported to increase with age (AIHW, 2005a). The slow onset and insidious nature of the condition translates to an illness that is often not diagnosed until it is clinically apparent (Reid et al., 2003). The delay in diagnosis can be compounded by the presence of co-morbidities, which may conceal COPD from prompt recognition.

COPD has been estimated to cost the Australian economy eight hundred million dollars annually (Crockett et al., 2002). This figure is most likely a conservative estimate, as it was based on economic figures from the early

1990s. The presence of co-morbidities adds to the costs of treating people with the condition (Crockett et al., 2002).

1.2.2 The Regional Perspective

In Victoria, the most common high volume Emergency Department (ED) presentations include chest pain, unstable angina, gastrointestinal tract disturbances, urinary tract infections, COPD, congestive heart failure and asthma (VEDCG, 2002). These conditions have been found to consume a significant amount of acute care public sector funding (Clinical Evaluation and Health Service Evaluation Unit, 1999; VEDCG, 2002). In addition, a patient's age may be considered as a predictor of hospital admission from the ED (VEDCG, 2002): see Table 1.1. The disproportionately high admission rate in older Victorians supports the notion that chronic and/or co morbid conditions remain the major consumers of acute care resources.

Table 1.1: Victorian Emergency Department Activity in 2000-2001:(VEDGC, 2002).

Age (Years)	Number of Victorians*	Patients	Presentations	Mean presentation per patient	Admissions rate per presentation (%)
<15	960,164	132,610	177,162	1.3	15.5
15-64	3,259,917	278,584	374,146	1.3	17.7
>65	637,147	88,178	129,029	1.5	46.2

* Source: Australian Bureau of Statistics 2001 dataset

This PhD project collected data from one hospital and compares these results with a those from a neighbouring hospital. Hospital A is located 22 kilometres North of the Central Business District of Melbourne and serves three municipalities, urban and rural. Hospital B, whose COPD patient group served as the control group for this study is located fifteen kilometres North West of the Central Business District of

Melbourne and serves five municipalities, urban and rural. A Melbourne study has reported that COPD inpatients across metropolitan public hospitals in Melbourne, are a homogenous group as measured by demographic and socio-economic variables, symptoms and quality of life (Lowe et al., 2003).

The 2001 Federal Census data and Local Government reports on the regions served by Hospitals A and B confirmed the comparability between these two regions (ABS, 2001; Census, 1996, 1998; 2001a; 2001b; 2001). Some demographic data of the catchment areas served by these two hospitals, are summarised in Table 1.2.

Table 1.2: Demographic profile of regions served by Hospital A & B

	Hospital A	**Hospital B**
Australian Born	63%	58%
English only spoken at home	59%	54%
Mean Household size (persons)	2.95	2.75
Median weekly Individual Income ($AUD)	317-416	300-399
Median weekly Household Income ($AUD)	783-949	717-866

The federal and local government census data, and the Lowe et al study (2003) support the suitability of using a control group, from Hospital B, for this project. The comparison of aggregate groups with comparable characteristics relevant to the study's outcomes has been a reported practice in randomized studies (Rossi, Lipsey, & Freeman, 2004). There is always the possibility that equal variances between the two hospitals regions is assumed, when this is untrue (a Type II error). The comparison of two unknown populations has been a recognized problem. The means of normal populations can be compared without assuming that unknown variances are homogenous (Tsakok, 2003).

COPD had been reported previously as a high volume separation in Victorian ED activity. A review of the ten most common unplanned admissions to

Hospital A's ED for 2001 confirmed COPD as a significant cause of unplanned presentation: see Table 1.3.

Table 1.3: The top ten presentations to Hospital A's ED for 2001

Rank	ADMISSION DESCRIPTION
1	**Respiratory infection/inflammation w/o cc**
2	Chest Pain
3	Abdominal Pain
4	**Bronchitis & asthma age < 50 w/o cc**
5	Poison/ Toxic effects of drugs
6	Oesophagitis
7	Unstable Angina
8	Circulatory disease with AMI
9	**COPD with catastrophic / severe consequences**
10	Heart Failure & Shock

Note: w/o cc: without catastrophic complications

A medical records audit of all case presentations to Hospital A since its inception in 1998 until 2001 was undertaken by me. This retrospective audit (n= 1067) demonstrated a 59% increase in COPD separations and a mean readmission rate of 20% in this period: see Figure 1.2. This equates to a rise in annual bed days for COPD from 1316 to 2408.

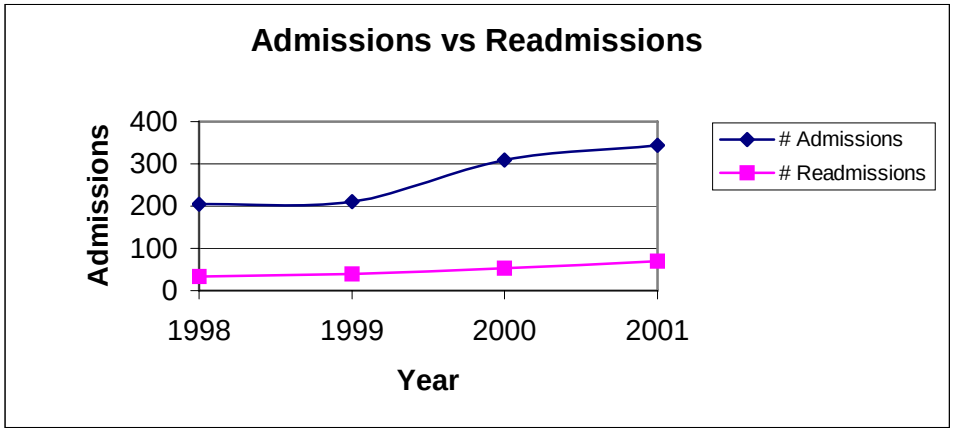


Figure 1.2: Separations for COPD at Hospital A 1988-2001.

The Victorian State data set had reported the mean length of stay (LOS) in an acute care facility for an exacerbation of COPD in 2001/2002 was 5.7 days (source: Health Information Services; Hospital A). The national mean LOS in an acute facility, for an exacerbation of COPD during the same period was 5.3 days (Frith, 2002). Earlier reports had cited the Australian national mean LOS for an inpatient admission was 5.7 days (Nosworthy, Campbell, Osborne, & Hines, 2001). The mean LOS at Hospital A as reported in Table 1.4 has been consistently above these figures.

Table1.4: Length Of Stay (days) at Hospital A for patients with a diagnosis of an exacerbation of COPD.

Year	Mean	Median	IQR_1	IQR_3	Range (days)
1998	7.4	5.5	3.3	9	1 to 44
1999	6.9	4	3	7	1 to 70
2000	7.5	5	2	8	1 to 93
2001	6.9	5	3	8	1 to 88

The number of repeat admissions for the same person, with an exacerbation of COPD has not reduced over time: see Figure 1.3. Along with an increase in patients requiring admission for an exacerbation of COPD, Hospital A had treated a significant number of patients admitted with COPD recorded as an additional diagnosis, in addition to, the primary need for hospitalisation. No data have been collated for the total number of patients with COPD cited as an additional diagnosis in 2001. The Health Information departments in Victorian Hospitals no longer collate these data.

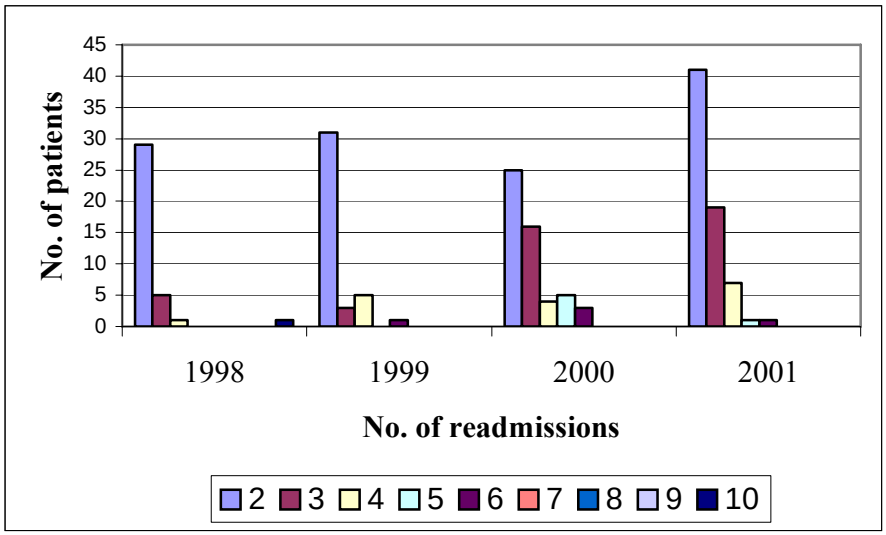


Figure 1.3: Patients vs. Readmissions with COPD from 1998-2001

A sample audit of the first fifty presentations (in 2001) to Hospital A with an exacerbation of COPD as their primary diagnosis (Harvey et al., 2005) identified the mean age of this population was 71.5 years, with a range of 54 – 91 years. The average age in this sample is consistent with the higher admission rate amongst older Victorians reported in Table 1.1. Presentation by gender was relatively even at 47% Female, 53% Male within the audit. This convenience sample is in contrast to the data for the Global Burden of COPD, which reports the presentation of three males to every two females with COPD (AIHW, 2002b). The audit identified that 96% of patients were found to have one pre-existing co- morbidity, and 76% had at least two or more co morbid conditions. The vast majority of patients resided in the community, with only four per cent residing in a Hostel or supported accommodation. Due to the increased demand for COPD management, the audit examined adherence to evidence based guidelines for the inpatient management of COPD. Concordance with the guidelines was generally less than 60% with, referral to pulmonary rehabilitation at 15%. The increased demand for health services by people with COPD and comorbid conditions provides evidence for the need to consider a model of health care beyond the acute care system.

1.3 Current health management strategies

COPD like many chronic conditions remains a condition that may be controlled but not cured. Efforts to improve the health of people with COPD include the widespread use of pharmacologic agents. Corticosteroids have been reported to offer relief from symptoms but will not alter the course of the disease process (Stanbrook, Kaplan, Juurlink, & Poole, 2002)**.** The use of anti -inflammatory treatment appears to be indicated in conjunction with other treatments (O'Brien & Ward, 2002; Wood-Baker, Walters, & Gibson, 2002). Surgical options include lung volume reduction surgery (LVRS) and transplantation. LVRS is neither a cure nor panacea (Cooper & Lefrak, 1996) and the benefits are reported to decline after two years (Snell et al., 1997)**.** Patients who are candidates for LVRS would be equally suitable for lung transplantation where the benefits are more long term (Snell et al., 1997). Therefore, strategies to maintain optimal health in people with COPD include the use of adjuvant therapies.

1.4 Adjuvant therapy

Adjuvant therapies can and do have a quantifiable impact over a number of health outcomes. There are a number of existing and novel adjuvant therapies available, for people living with COPD. However, this project will concentrate on just two. Pulmonary rehabilitation and the Stanford model Chronic Disease Self Management Program (CDSMP) are two interventions that have both been able to demonstrate an effect in studies of various design, timeframes and mapped to a number of dependent variables, albeit with different population groups.

The Stanford CDSMP was reported as devised from an analysis of seventy articles on chronic disease patient education programs (Lorig, Sobel et al., 1999). The common components were identified from within these programs. This synthesis of reported components identified that: the management of symptoms, communication with health care providers and significant others, the use of community resources, smoking cessation, exercise, nutrition, correct

use of medication, using stress reduction techniques, managing emergency situations, the emotional sequalae of illness, were common themes to these programs. Following the compilation of these data, Lorig et al reported on the formation of focus groups and the use of thematic analysis to identify the needs of the chronically unwell (Lorig, Sobel et al., 1999). The thematic analysis and literature review shaped the Stanford model CDSMP. The CDSMP was a collaborative effort between Stanford University, and the Kaiser Permanente health network. The initial CDSMP was trialed in Southern California (USA) in 1977 (Pepper-Burke, 2003).

The Stanford model CDSMP course has been offered in Australia as a six-week program covering the use of medications, dealing with fear, anger and depression, fatigue management, effective communication strategies with your health care provider, problem solving, decision making, use of cognitive symptom management techniques, nutrition and exercise strategies. The content of this six-week program is delivered with the aid of a highly structured manual. This manual was adapted by the licensee Arthritis Victoria, to suit Australian conditions (Lorig & Arthritis Victoria, 1999). The program facilitates the formation of weekly action plans, feedback, and role modelling of behaviour, group problem solving, individual decision-making and encouragement of the participants to engage in activity. The CDSMP is one innovative treatment option that has generated an effect in the arthritic population group and other cohorts of groups with various chronic disease conditions. This treatment option has been reported to achieve a delay in disease progression, reduced hospitalisations as well as to enhance patient self-management skills and self-efficacy levels.

Use of the Stanford model CDSMP in the USA has been reported as achieving a reduced need for hospitalisations and/or length of stay as an inpatient in an acute facility (Lorig, Ritter et al., 2001). The literature that reports on this innovative therapy will be examined in Chapter Two. The six-week Stanford model CDSMP is aligned with the principles of self-efficacy theory as

postulated by Bandura (1982). The research undertaken in self-efficacy will be examined in Chapter Three. In summary, Bandura considered that a person's perception of their ability to successfully engage in a behaviour would influence their future uptake of that behaviour.

The alternative adjuvant therapy this project evaluated was pulmonary rehabilitation. A pulmonary rehabilitation program directs participants in exercise training and symptom control. Pulmonary rehabilitation has been defined as:

> **"**A multi disciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimise physical and social performance and autonomy" (ATS, 1999b ,p.1666).

The selection criterion for involvement in this therapy encompasses all participants who are willing and capable to attend a pulmonary rehabilitation program**.** The self reporting of symptoms such as dyspnoea, and restriction of function in daily living are an indication for program participation (ATS, 1999b). This therapy aims to encourage all participants to continue to engage in activity on the days they are not in the gymnasium. The primary goal is to optimise the participant's independence and function via exercise training, and guidance in methods of symptom control (BTS, 1997). Secondary goals include "improved quality of life and decreased hospitalisations"(Garvey, 1998 ,p.596). Despite the irreversible nature of COPD, there have been benefits reported from participating in a pulmonary rehabilitation program. These benefits include a reduction in symptoms such as dyspnoea, improved perceived mastery of the condition, quality of life, affect and, a reduced need for hospitalisation and/or, a reduced length of stay (Bott & Singh, 1998; Cambach, Wagenaar, Koelman, Ton van Keimpema, & Kemper, 1999; de Torres et al., 2002). The reported benefits that participation in pulmonary rehabilitation may confer will be reviewed in Chapter Two.

A summary of the reported benefits from both of these adjuvant therapies suggests that they are therapies with comparable outcomes as presented in Table 1.5.

Table 1.5: Summary of the reported health outcomes following PRP and CDSMP participation

Pulmonary Rehabilitation	**Stanford Model CDSMP**
↑ Exercise Tolerance	↑ Functional Activity
↓Hospitalisation ± Length of stay	↓Hospitalisation ± Length of stay
↑ Mood + Motivation	↓ Depression
↑ Health Related Quality of Life	↑ Self Rated Health
↑Self Efficacy	↑Self Efficacy
↓ Dyspnoea	↑ Symptom Control

Both programs have been reported to confer benefits on the participant with a chronic condition with respect to delay of disease progression, increased functional capacity and reduced need for hospitalisations. Until now, neither of these applied health care interventions has been subject to direct comparison of their effectiveness for people with COPD. Both of these interventions need to be examined to further evaluate their merit, and compare the relative benefits which participation in these interventions may confer with regard to three types of outcomes: physiological, psychological and economic.

1.4.1 Current Practices in Health Management Support

Access to pulmonary rehabilitation programs (PRP) in Victoria remains limited. The Australian Lung Foundation cites in their report that for every two hundred people with COPD only one will be able to access a program (Crockett et al., 2002; Nosworthy et al., 2001). There are at least five publicly funded pulmonary rehabilitation (PRP) programs available in metropolitan Melbourne (Australian Lung Foundation, 2003). There are PRPs available in private hospitals in the metropolitan region for those who have private health

insurance or, can afford to pay. COPD's ranking in the top three chronic conditions affecting Australians (AIHW, 2002b) coupled with an aging population, strongly suggests the urgency for increasing access to interventions that delay disease progression, and promote wellness and self management skills.

1.4.2 Evaluating the management and treatment of COPD

An evaluation of contemporary treatment modalities needs to include improvements in the person rather than just the symptoms and encompass the concept of Quality Adjusted Life Years (QALY) and burden of disease. A comprehensive evaluation of effective COPD management should therefore encompass all health (physiological, psychological and economic) outcomes. Innovative treatment options that have demonstrated an effect on quality of life, the number of hospitalisations, length of stay, or a delay in disease progression need to be implemented as a matter of some urgency.

Therefore Hospital A's strategy in 2002, was to create and evaluate a COPD treatment program to reduce the burden of disease. A randomised controlled trial to evaluate the relative effectiveness of pulmonary rehabilitation and, the Stanford Model Chronic Disease Self Management Program (CDSMP) was implemented by establishing these two adjuvant therapies onsite at Hospital A, which we have reported (Murphy, Campbell, Saunders, & Berlowitz, 2005; Murphy, Saunders, Campbell, Jackson, & Berlowitz, 2003). Both programs aimed to generate optimal wellness in the COPD participants. Both interventions aimed for similar outcomes, namely a delay in disease progression, unplanned admissions, optimal psychological well being, confidence to manage their health, and improved functional status.

The findings of this study are designed to contribute to finding ways to meet the challenges of provision of care that facilitates a health related quality of life coupled with a model that is economically sustainable.

Chapter Two Literature Review

2.1 Introduction

The search strategies undertaken for this study included an electronic database search of Medline, CINAHL and the Cochrane database using the following terms: COPD, obstructive lung disease, disease severity, quality of life, quality adjusted life year, cost utility, self efficacy, stages of change, reasoned action, health models, dyspnoea, depression, self management program, pulmonary rehabilitation, maintenance, nursing, clinical trial, and pharmacoeconomics.

This chapter outlines a synthesis of the causes and classifications of COPD, indicators of disease progression, the evaluations undertaken in pulmonary rehabilitation and self-management programs and the ambitions of these adjuvant therapies. Following this, an introduction to the role of economic evaluation is discussed. Overall, this chapter and the next chapter on health models were designed to set the scene for the research questions that are presented at the end of Chapter Three.

2.2 Causes and classifications of COPD

Chronic Obstructive Pulmonary Disease (COPD) is a systemic, permanent and progressive condition, and there are a number of catalysts involved in its development. Smoking is the cardinal risk factor in the development of COPD and continuation, the most significant determinant for disease progression (Mannino, 2002; McKenzie et al., 2003). Smoking is defined as the daily smoking of tobacco products, including packet cigarettes, roll your own cigarettes, pipes and cigars (AIHW, 2002b). Clinicians calculate the quantity of smoking by the concept of pack years. A pack year is determined by a simple formula and is independent of whether the client is a current or reformed smoker (Lowe et al., 2003). A cigarette pack year history was defined by the British Thoracic Society (1997) as follows:

Σ Pack Years = (Number of cigarettes/day) x number of years smoked

A history of more than 20 pack years of smoking is considered to be a significant risk factor for the development of COPD (BTS, 1997). In the past, the causal links between COPD and smoking resulted in a public perception that COPD was a self-inflicted disease (Gerald & Bailey, 2002; Tan, 2002; Williams & Bury, 1989). Less then 15% of smokers, develop clinically significant COPD (Croxton et al., 2003; Mannino, 2002; Regional COPD working group, 2003). However, continuing to smoke accelerates the decline of respiratory function in susceptible individuals (Fletcher & Peto, 1977; Lacasse, Maltais, & Goldstein, 2002; McKenzie et al., 2003): see Figure 2.1.

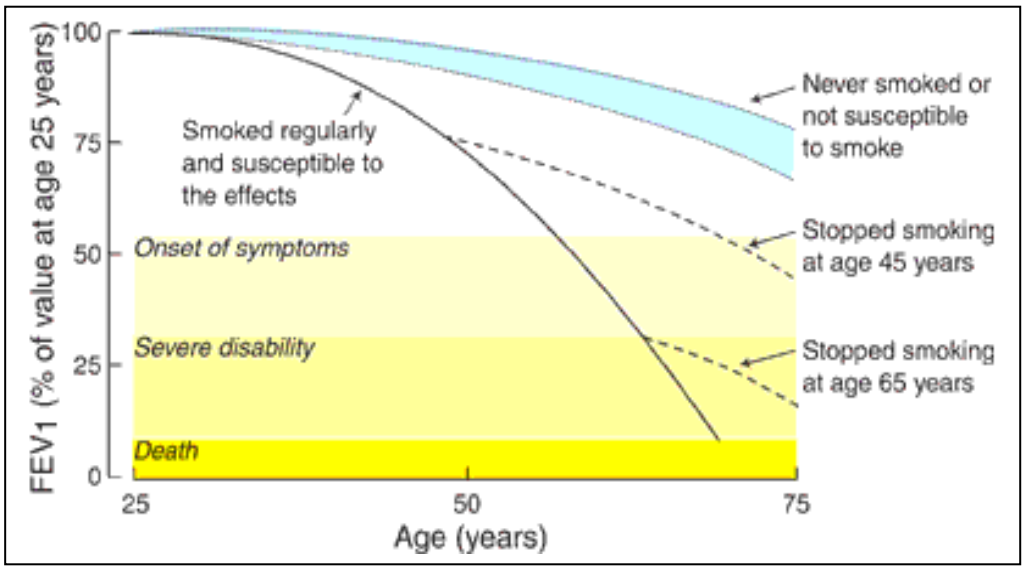


Figure 2.1: Smoking status and health outcomes: (Fletcher & Peto, 1977 ,p.1646).

Other factors implicated in the development and progression of COPD include environmental and occupational pollutants, genetic predisposition, bronchial hyper-responsiveness and respiratory infections (Bach, Brown, Gelfand, & McCrory, 2001; Chen & Mannino, 1999; Chitkara & Sarinas, 2002; Gerald & Bailey, 2002; Mannino, 2002; Pauwels, Buist, Ma, Jenkins, & Hurd, 2001; Sutherland & Cherniack, 2004). COPD has a variable natural history that no medication has been able to cure (BTS, 1997). Disease progression in susceptible individuals is most likely dependent upon the synergistic actions of the mechanisms involved in the development of COPD.

COPD creates significant changes in cell structure, and in muscle and organ function (Wouters, Creutzberg, & Schols, 2002). The immunopathological effects of COPD include activation of the circulating inflammatory cells including neutrophils, Interleukin-1, tumour necrosis factor-alpha (TNF-α), and C-reactive protein. These circulating inflammatory cells are thought to trigger an imbalance between oxidants and anti oxidants. Cigarette smoke and neutrophils both contribute to oxidative stress, and have been considered to be catalysts to the pulmonary inflammatory response (Agusti et al., 2003; Croxton et al., 2003; Wouters et al., 2002). Oxidative stress has also been reported as a contributor to muscle myopathy, yet the extent of oxidative damage is highly variable between COPD patients (Couillard, Koechlin, Cristol, Varray, & Prefaut, 2002; Troosters, Casaburi, Gosselink, & Decramer, 2005). In order to minimise the deleterious effects of oxidative stress, catalysts that precipitate this cascade need to be minimised. Smoking cessation is a vital outcome (Frith, 2002).

The systemic effects of COPD on cardiovascular structure and function include a chronic inflammation of the central and peripheral airways, and pulmonary vessels (Gronkiewicz & Borkgren-Okonek, 2004). The inflammation in vascularized tissues is a localisedd response, mediated by bacterial infection and /or cell and tissue injury (Pettersen & Adler, 2002). In the central airways, inflammation results in an increase in goblet cells that cause hyper-secretion of mucus (Gronkiewicz & Borkgren-Okonek, 2004). The peripheral airways undergo repeated attempts at tissue wall repair, and with time, this regenerative process fails. Destruction of the alveolar wall and architectural remodelling occurs, resulting in a narrowing of the airway lumen, expiratory airflow limitation and disease progression (Farquhar & Fantasia, 2005; Gronkiewicz & Borkgren-Okonek, 2004; Hogg et al., 2004). Ventilation abnormalities occur with COPD due to the airway inflammation, bronchoconstriction, increased mucus secretion, and oedema. Perfusion abnormalities in COPD arise from hypoxic induced vasoconstriction of the capillary beds. Impaired ventilation and perfusion leads to hypoxemia. In addition to hypoxemia, mechanical disadvantages in the COPD patient also develop. The primary cause of adverse lung mechanics is hyperinflation.

Hyperinflation of the lungs has been described as having two components; static and dynamic (Mergoni & Rossi, 2001). The loss of elastic recoil (static hyperinflation) and incomplete expiratory airflow (dynamic hyperinflation) leads to air trapping and a reduced inspiratory capacity (Casanova et al., 2005; Diaz et al., 2001). The effects of incomplete and prolonged expiration accounts for the reduced exercise tolerance, increased work of breathing, and dyspnoea experienced by people with COPD (Alvisi, Mirkovic, Nesme, Guerin, & Milic-Emili, 2003; Barbarito, Ceriana, & Nava, 2001; Decramer, 2001; Haccoun, Smountas, Gibbons, Bourbeau, & Lands, 2002; ODonnell, 2001; Polkey, 2002; Sutherland & Cherniack, 2004). In a study of respiratory mechanics in clinically stable COPD patients (n=96), a strong correlation was reported between FEV_1 and dynamic hyperinflation ($r = - 0.56$, $P<0.001$), and $PaCO_2$ and dynamic hyperinflation ($r = 0.6$, $P<0.001$). This report outlined that the severity of COPD promotes hyperinflation of the lungs, and hyperinflation is a catalyst for hypoventilation (Haluszka, Chartrand, Grassino, & Milic-Emili, 1990). Hyperinflation and flow limitation impact negatively on the lung's mechanics and explain the difficulties experienced by people living with COPD. "Even at rest, patients with COPD work harder than patients without COPD because they have to overcome dynamic hyperinflation and airflow obstruction which limit their tidal volume" (Sin & Man, 2003 , p.2306).

Perfusion abnormalities in COPD arise from hypoxic induced vasoconstriction of the capillary beds. The pulmonary ventilation/perfusion (V/Q) abnormalities, and hyperinflation contribute to increased pulmonary vascular resistance (PVR), and respiratory muscle fatigue (Gronkiewicz & Borkgren-Okonek, 2004). Increased PVR and hypoxemia require the right heart pump to work harder and results, over time in hypertrophy, remodelling and Cor Pulmonale (Farquhar & Fantasia, 2005; Sietsema, 2001). The incidence of right ventricular hypertrophy is thought to occur in 40% of patients with moderate levels of COPD (i.e. $FEV_1 < 1000$ mls) (McKenzie et al., 2003). In addition, the left ventricle may also be compromised by hyperinflation, which generates an increased work of afterload (Mergoni & Rossi, 2001). With disease progression, the effects of COPD on cardiovascular function may

result in ventricular dysfunction, pulmonary hypertension, hypoxemia and hypercapnia. Not surprisingly, heart disease had been reported in the literature as a frequent concomitant condition with COPD (Huiart, Ernst, & Suissa, 2005; Schroeder et al., 2003; Sin & Man, 2003).

The systemic effects of COPD on skeletal muscle accounts for the common report of mobility, being limited by dyspnoea (Dyer, Singh, Stockley, Sinclair, & Hill, 2002; Redelmeier, Bayoumi, Goldstein, & Guyatt, 1997). The skeletal muscles involved with respiration are the intercostals and the diaphragm (Larson, Covey, & Corbridge, 2002; Levine, Kaiser, Leferovich, & Tikunov, 1997). Blood flow may be diverted away from exercising lower limb muscle to the diaphragm, to meet the oxygen requirements of the respiratory muscles. This phenomena is referred to as circulatory steal (Sietsema, 2001). In COPD, due to the competing of the central and peripheral muscle demands for oxygen, the oxygen requirements of lower limb muscles are supplemented by anaerobic metabolism. This compounds the difficulties of ambulation for people with COPD, as the recruitment of anaerobic pathways contributes to the development of dyspnoea (Haccoun et al., 2002; Polkey, 2002). Exertional oxygen desaturation observed in some COPD patients is considered a consequence of these ventilatory and skeletal limitations. Therefore the addition of supplemental oxygen to hypoxemic patients with COPD has been found to reduce dynamic hyperinflation, dyspnoea, and improve exercise tolerance (Alvisi et al., 2003; Casaburi, 2001); reduce PVR (Bach et al., 2001; Fujimoto, Matsuzawa, Yamaguchi, Koizumi, & Kubo, 2002; Sin & Man, 2003); reduce ventilatory requirements, and circulating lactate levels (Nici et al., 2006; Troosters et al., 2005).

In a synthesis of studies, supplementary oxygen therapy of up to six litres per minute via nasal cannulae had been reported to improve exercise tolerance, and reduce dyspnoea, in a dose dependent manner. This outcome suggests that increased arterial oxygenation is the catalyst for functional gains (Snider, 2002). The method and duration of ambulatory oxygen delivery has been considered in the literature as having a significant impact on health outcomes (Jolly et al., 2001; Petty, 1993). The efficacy of continuous flow oxygen

therapy, when compared with an oxygen-conserving demand delivery system has been reported to confer greater benefits, as evidenced via a timed walking test (Roberts, Bell, & Wedzicha, 1996). In this project for pragmatic reasons, all participants who recorded an exertional oxygen desaturation less than 85% via cutaneous pulse oximetry were exercised with continuous intranasal oxygen therapy to reduce cardiovascular strain, and prolong activity tolerance.

The systemic limitations that arise with COPD are profound and complex (Cooper, 1995). The inter-relationships of these effects are illustrated in Figure 2.2.

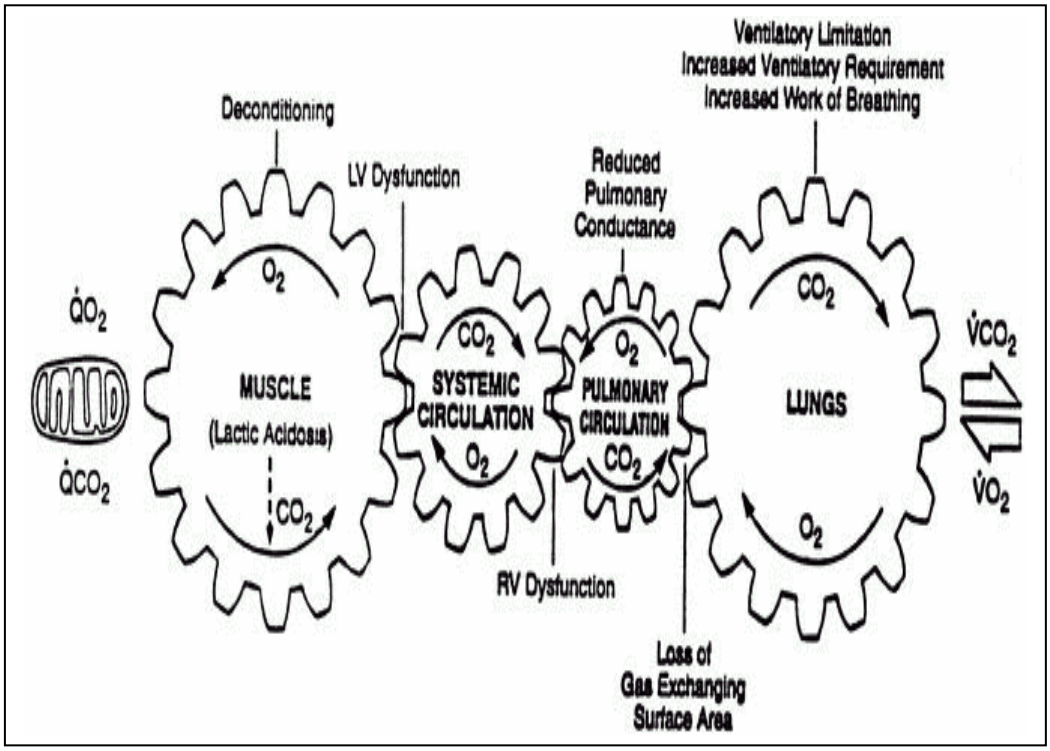


Figure 2.2: The systemic interrelationships in COPD:(Cooper, 1995 ,p.148).

Body Mass Index (BMI) may also be regarded as a secondary measure of the systemic effects of COPD. BMI is calculated as weight in kilograms divided by the square of the height in metres. Anecdotal reports in the literature indicated unintentional weight loss in people with COPD which had been attributed to "depression, dyspnoea when eating, difficulty getting out of the house to shop for food and fatigue associated with preparing food" (Larson et al., 2002 p. 322). However, a number of studies have identified a low BMI in

people with COPD may not be a consequence of anorexia but, probably due to systemic inflammation, and a catabolic state consistent with the increased work of breathing (Agusti et al., 2003; Larson et al., 2002; Prescott et al., 2002). Elevated levels of inflammatory markers such as Interleukin-6 and TNF- α levels have been reported in clinically stable people with COPD who had a low BMI (Eid et al., 2001; Prescott et al., 2002). A meta analysis of supplemental nutritional support in individuals with COPD reported no beneficial effect on BMI, lung function or exercise capacity (Ferreira, Brooks, Lacasse, Goldstein, & White, 2002). The significance of BMI as a risk factor for morbidity and mortality was illustrated by the outcomes of the Copenhagen City heart study (Prescott et al., 2002). This large scale (n= 11,135), longitudinal study reviewed BMI stratified by FEV_1 as a predictor of health outcomes in COPD over a five-year period. In subjects with severe COPD, being overweight (BMI 25-30), or obese (BMI >30) conferred protective benefits not evidenced in those underweight. In a more recent study, the outcomes of the Copenhagen study were supported (Wannamethee, Shaper, & Whincup, 2005). There has been no direct cause for unintentional weight loss identified in the literature. However, BMI is a frequent measurement, recorded in COPD evaluations, as it is a poorly understood but, recognized as an indicator of prognosis and mortality, independent of FEV_1, adjustment for age or, smoking history (Harik-Khan, Fleg, & Wise, 2002; Larson et al., 2002; Pitulainen et al., 2002; Prescott et al., 2002; Wouters et al., 2002). BMI was measured in this study to describe the project's sample and, monitored with each assessment over the 12-month follow up.

There have been a number of precipitants reported in the literature in the development of COPD. Although COPD is primarily a respiratory condition, the systemic effects that arise with disease progression are quite profound.

The next section reports on the classification systems used to describe the severity of COPD.

2.2.1 The diagnosis and classification systems in COPD

The diagnosis of COPD is made on reported symptoms and clinical investigations. A patient presents with one or a combination of dyspnoea, cough and sputum production. In addition to the patient's history, the diagnosis of COPD can be confirmed by functional, radiological and histopathological investigations (Chitkara & Sarinas, 2002; National Collaborating Centre for Chronic Conditions, 2004). In addition, a number of clinical investigations are employed to detect concomitant conditions such as anaemia or polycythemia, and to exclude other causes for the presenting symptoms (BTS, 1997; National Collaborating Centre for Chronic Conditions, 2004). Spirometry is a functional test, that is largely perceived as 'the gold standard' for the diagnosis of COPD (Gerald & Bailey, 2002; Halbert, Isonaka, George, & Iqbal, 2003; McKenzie et al., 2003; Pauwels et al., 2001).

2.2.1.1 Spirometry.

Spirometry is a non-invasive quantitative measurement of respiratory function which is used to diagnose and classify airflow limitation (Crapo, 1994; Glady, Aaron, Lunau, Clinch, & Dales, 2003). This functional investigation may include the assessment of inspiratory capacity, diffusing capacity, forced expiratory capacity in one second (FEV_1) and the Forced Vital Capacity (FVC). FEV_1 is measured in the first second of measuring the FVC. Airway resistance increases with the degree of the patient's airflow limitation. Therefore, FEV_1 can be regarded as a measure of the severity of COPD. When the FEV_1 falls below 80% predicted, and the forced expiratory (FEV_1/FVC) ratio is less than 70% predicted, airway obstruction is present (ATS, 1995b; BTS, 1997). The type of respiratory condition can be confirmed by the forced expiratory ratio. In obstructive lung conditions, the FEV_1 and FEV_1/FVC ratio are both low measurements (Bach et al., 2001). Bronchodilator use can result in a degree of airway reversibility. The percentage change in FEV_1 post bronchodilator use can be variable in COPD (Celli, Halbert, Isonaka, & Schau, 2003) but, the forced expiratory ratio remains consistently low (Jenkins, 2003;

McKenzie et al., 2003). In contrast, a low FEV_1 and normal FEV_1/FVC ratio indicates a restrictive lung disease (Hess et al., 2002). The severity of the person's COPD can be measured using expiratory airflow limitation with, FEV_1 % predicted from population norms. There are a number of reported reference tables in the literature that take into account ethnicity, height, gender, and age when comparing results with population norms (TSANZ, 2005). In Australia, respiratory function tests are usually performed in accordance with standard principles (ATS, 1995a). The values obtained are expressed at body temperature, ambient pressure, saturated with water vapour (BTPS), in absolute units (l or l/s) and, as a percentage of predicted normal values. The carbon monoxide pulmonary diffusing capacity (TLCO), may be measured using the single breath technique modified by Krough. The diffusing capacity indicates the available surface area for gas exchange. This figure is reduced with emphysema, and often normal with asthma (Hughes & Pride, 2000). The diffusing capacity (TLCO) can be considered by a directly measured value or, as a percentage of predicted normal for age, sex, height and weight. There are a number of reference tables of the predicted normal values, that enable comparison of the results with population norms (TSANZ, 2005).

2.2.1.1.1 SPIROMETRIC PARAMETERS FOR DISEASE SEVERITY

Despite widely disseminated guidelines by the American (ATS), British (BTS) and, European Respiratory Societies (ERS), and more recently, the collaborative global initiative for chronic obstructive lung disease (GOLD) workshop report, there has been no consensus between these guidelines for classifying disease severity based on spirometric criteria (Iqbal, Schloss, George, & Isonaka, 2002; Reid et al., 2003). The spirometric criteria that classify the severity of COPD espoused by the Australian and New Zealand (TSANZ), and other respiratory societies (ATS, 1995b; BTS, 1997; McKenzie et al., 2003; NHLBI / WHO, 2001; Siafakas et al., 1995), have been summarized in Table 2.1.

Table 2.1: Parameters for the severity of COPD

Respiratory Society	Classification	FEV_1/FEV_1 % predicted
ATS	Stage I	≥ 0.50
	Stage II	0.35 - 0.49
	Stage III	< 0.35
BTS	Mild	0.60-0.79
	Moderate	0.40-0.59
	Severe	< 0.40
ERS	Mild	≥ 0.70
	Moderate	0.50- 0.69
	Severe	< 0.50
GOLD	Stage 0 At risk	Normal spirometry
	Stage I Mild	≥ 0.80
	Stage II a Moderate	0.50 - 0.79
	Stage II b Moderate	0.30-0.49
	Stage III Severe	< 0.30
TSANZ	Mild	0.60 - 0.80
	Moderate	0.40- 0.59
	Severe	< 0.40

Both the ATS and BTS guidelines have demonstrated some correlation between the disease severity and health related quality of life (HRQoL) in cross sectional studies of male outpatients with COPD (Ferrer et al., 1997; Hajiro, Nishimura, Tsukino, Ikeda, & Oga, 2000). The Hajiro study identified a correlation between HRQoL with severe COPD ($r = -0.24$, $P < 0.05$) (Hajiro et al., 2000). In contrast, a cross sectional study ($n = 321$) using the ATS staging criteria, had demonstrated a moderate to strong correlation ($r = 0.27$-0.51) between spirometric parameters, and HRQoL as measured with the same

HRQoL outcome measure (Ferrer et al., 1997). The Ferrer study suggests that the ATS criteria may stratify disease severity more closely with HRQoL than the BTS staging system. More recently, the guidelines of the GOLD workshop report were formulated (NHLBI / WHO, 2001). Due to its bridging between gradings from multiple scientific bodies, the GOLD classification system had been used in this study to describe the project's sample.

There have been mixed reports in the literature of the correlation between disease staging with symptoms. There has been a reported weak correlation between pulmonary function and symptoms (Hay et al., 1992; Selim et al., 1997), and reports of a strong correlation between spirometric readings with dyspnoea (Bestall et al., 1999). Objective data such as FEV_1 does not always correlate with the patient's perception of their wellbeing. These reports would suggest that the evaluation of the effectiveness of interventions applied in a COPD sample requires the inclusion of both subjective and objective measures to fairly determine their efficacy, which we have discussed in the peer reviewed literature (Murphy, Saunders, & Campbell, 2007). The classification of COPD by FEV_1 has been used in this project to simply describe the respiratory impairment measured at baseline, in the study's sample.

2.3 Indicators of disease progression in COPD

2.3.1 Exacerbations of COPD

Despite the prognostic significance of an exacerbation of COPD on morbidity and mortality, there remains no consensus on the definition of an exacerbation (Rodriguez-Roisin, 2000). However, an exacerbation is thought to include the report of worsening dyspnoea or wheeze and/or, variation in cough, sputum quantity or character (Dowson, Guest, & Stockley, 2002; Oostenbrink & Molken Rutten - van, 2004) of greater than two days duration (Hurst, Wilkinson, Donaldson, & Wedzicha, 2004; Wilkinson, Donaldson, Hurst, Seemungal, & Wedzicha, 2004) requiring a change to regular medication usage (Rodriguez-Roisin, 2000).

An exacerbation of COPD is clinically significant, as it correlates with disease progression, and a reduction in lung function (Donaldson, Seemungal, Bhowmik, & Wedzicha, 2002; Gerald & Bailey, 2002; Wedzicha, 2002; Wilkinson et al., 2004), and reduced HRQoL (Bach et al., 2001; Haughney et al., 2005; Miravitlles et al., 2004; Oostenbrink & Molken Rutten - van, 2004; Seemungal, Donaldson, Bhowmik, Jeffries, & Wedzicha, 2000; Seemungal et al., 1998; Spencer, Calverley, Burge, & Jones, 2004; Wilkinson et al., 2004). The aetiology of an exacerbation of COPD is variable. Environmental, bacterial, viral and co-morbid health issues have been cited and summarily reported as mechanisms that may trigger an exacerbation of COPD (Gerald & Bailey, 2002; McKenzie et al., 2003; Wedzicha, 2002).

Neutrophils are a significant inflammatory marker of an exacerbation (as evidenced by sputum cultures, and bronchial biopsies) (Barnes, 2000). The recruitment of neutrophils as a first line of defence at the site of injury or inflammation leads to "increased vascular permeability, oedema, obstruction and increased responsiveness and secretions" (Pettersen & Adler, 2002 p. 145s). An acute exacerbation of COPD is the most common cause for hospitalisation in people with the condition with, a 12 month mortality rate post hospitalisation close to 23% (Groenewegen, Schols, & Wouters, 2003).

Exacerbations of COPD, the need for hospitalisation and, mortality rates have been reported to be closely correlated to FEV_1 classifications (Jenkins, 2003). In a study of 132 patients with longitudinal follow up (918 days), the frequency of an exacerbation was proportional to the patient's disease severity as stratified by the GOLD classification system. Recovery time and symptoms were reported to increase with the frequency of each exacerbation. In this study, participants had recorded a mean exacerbation rate of between two and three exacerbations per year (Donaldson et al., 2003). This outcome is supported by further reports in the literature that people with moderate to severe COPD record a mean of two exacerbations per year (Miravitlles et al., 2004). The patient's history of past exacerbations had also been reported as the greatest predictor of a future event (Miravitlles et al., 2004; Seemungal et al., 1998).

An exacerbation of COPD may not always be readily reported by the patient to the treating physician. A prospective controlled study evaluated whether people with COPD who actively engaged in prompt symptom management would potentially offset an exacerbation and delay disease progression (Wilkinson et al., 2004). Results revealed that subjects who did not seek treatment for their change in symptoms recovered more slowly (10.7 vs. 6.9 days, $P<0.001$), were more likely to be hospitalised (rho = 0.21, $P=0.04$) and reported worse HRQoL than their counterparts who sought medical assistance. These researchers concluded, programs directed at symptom management were needed to reduce morbidity in COPD (Wilkinson et al., 2004). Randomised controlled trials of participants in a pulmonary rehabilitation study have demonstrated a significantly reduced length of stay in hospital following an exacerbation of the condition as compared to a control group (Griffiths, Burr et al., 2000a). This outcome adds further support to the notion that treatments aimed at improving symptom control, and well being can result in a reduction of healthcare usage.

The classification systems of COPD disease severity have been examined to determine their validity in identifying possible hospital readmissions for an exacerbation. A prospective study (n=67) with longitudinal follow up (18 months) was undertaken to evaluate the correlation between the rate of hospital admissions for an exacerbation and the ATS, BTS, ERS and GOLD guidelines for disease severity (Tsoumakidou et al., 2004). Participants with greater than 15% reversibility in their spirometric measurements, and concomitant systemic conditions were excluded from this study. There was no correlation between disease severity as described by the ATS or BTS guidelines with hospital admissions for an exacerbation of COPD. However, a significant but weak correlation, between admissions with, the ERS criteria ($P = 0.02$, $r = 0.24$), and the GOLD criteria ($P = 0.02$, $r = 0.29$) was demonstrated. Whilst this report was limited by a small sample size, these findings suggest the utility of the GOLD disease staging criteria when examining health resource use in a sample COPD population.

The largest cost of care for people with COPD comprises unplanned inpatient admissions due to an exacerbation of the condition (Chapman, Bourbeau, & Rance, 2003; National Collaborating Centre for Chronic Conditions, 2004; Sullivan, Ramsey, & Lee, 2000; Wilson, Devine, & So, 2000). Therefore, in the 2003 Australian and New Zealand COPD-X guidelines, the expert panel proposed that patients be taught symptom recognition and timely management to contain and/or offset disease progression. The use of an action plan and self-management strategies were highlighted as possible methods to up skill the patient and their carers (McKenzie et al., 2003). One of the ambitions of this study was the evaluation of a self-management program in people with COPD as compared to a more established intervention within this population group.

2.3.2. Functional Status

Functional ability and morbidity are often reported in the literature with the severity of COPD determined by FEV_1 (Pellegrino et al., 2005). Reduced functional status has been identified in the literature as a key feature of disease progression in COPD (O'Shea, Taylor, & Paratz, 2004). Therefore the improvement and maintenance of functional status has remained a central goal in the management of COPD (Carter et al., 2003; Dyer et al., 2002; McKenzie et al., 2003; Redelmeier et al., 1997). Functional capacity, and general activity levels, had been reported in two COPD studies as greater prognostic indicators of survival post pulmonary rehabilitation program (PRP) attendance than gender, BMI or, social status (Bowen et al., 2000; Gerardi, Lovett, Benoit-Connors, Reardon, & ZuWallack, 1996).

A conceptual model (Figure 2.3) that described the components of functional status has been reported in the literature (Leidy, 1994). These components have been described as functional capacity, functional performance, functional reserve and utilization of functional capacity. ZuWallack reported that these components of functional status had both a cause and effect on health outcomes in COPD (ZuWallack, 2003).

Functional capacity describes activity at near maximum ability. Functional performance corresponds to the level of activity expended in daily activity. Functional reserve is the difference between these two components. In addition, functional reserve and capacity utilization refer to the store the participants draws from in the short term, to address the need (ZuWallack, 2003).

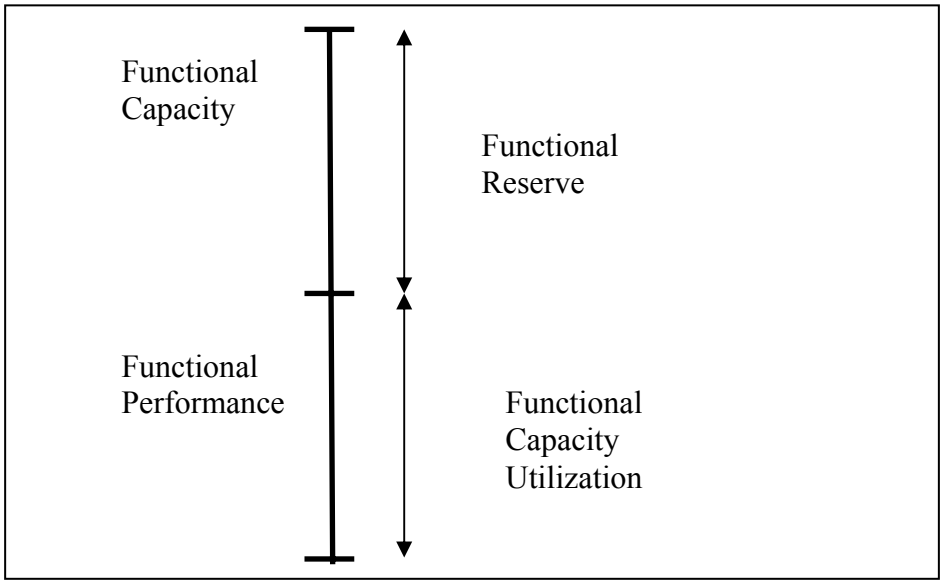


Figure 2.3: The components of functional status: (ZuWallack, 2003 ,p.230)

In the general population, advanced years had been reported as an antecedent to reduced functional status (Franssen, Broekhuizen, Janssen, Wouters, & Schols, 2004). However, a meta analysis of randomised controlled trials involving older subjects reported that age was not a barrier to generating significant increases in functional activity (Conn, Minor, Burks, Rantz, & Pomeroy, 2003). In COPD, the literature has reported direct and indirect impediments to functional activity to include: gas exchange abnormalities, cardiac function, reduced threshold for lactic acidosis, symptoms (e.g. breathlessness), and skeletal muscle weakness (Agusti et al., 2003; Garcia-Aymerich et al., 2004; Graydon, Ross, Webster, Goldstein, & Avendano, 1995; Lareau, Breslin, & Meek, 1996; Leidy, 1995; Reishtein, 2005).

There have been mixed reports from large cross sectional studies that have examined the relationship between functional status and respiratory

impairment. There have been reports of a strong correlation (Belza et al., 2001; Myint et al., 2005; Oga et al., 2002; Schonhofer, Ardes, Geibel, Kohler, & Jones, 1997), and no significant relationship between ambulation and FEV_1 has also been reported (Prigatano, Wright, & Levin, 1984; Sin, Jones, Mannino, & Paul Man, 2004; Singh & Morgan, 2001; Weaver & Narsavage, 1992). In contrast, psychosocial determinants of functional status in COPD has for some time been regarded as largely an under examined area (Leidy, 1995). There has been speculation in the literature whether functional status impacts on mood or vice versa (Graydon et al., 1995). Small scale studies in COPD have reported that the presence of anxiety, depression or stress were not determinants of functional status (Katz et al., 2005; Kim et al., 2000; Light, Merrill, Despars, Gordon, & Mutalipassi, 1985; Prigatano et al., 1984; Toshima, Blumberg, Ries, & Kaplan, 1992). Conversely, other COPD studies have reported a significant relationship between functional capacity and mood ($r = - 0.40$, $P<0.01$) (Weaver & Narsavage, 1992).

The literature has reported mixed results on the association between functional status and health care use in COPD. A strong association between reduced mobility in COPD, and health resource use has been reported (Mador & Bozkanat, 2001; O'Shea et al., 2004). In contrast, one small scale study in the USA has reported that outpatient based health care usage was associated with disease severity, and not functional status in people burdened by COPD (Kim et al., 2000).

With a chronic illness, the ability to maintain autonomy and independence in day to day functioning remains an important clinical outcome (Leidy, 1995). However, there are conflicts in the literature as to whether functional status is a variable that may influence HRQoL (Anderson & Burckhardt, 1999) or, constitutes a component of HRQoL (Katula, Rejeski, Wickley, & Berry, 2004; ZuWallack, 2003). Researchers have reported functional status as both a component, and predictor of HRQoL (Leidy, 1995). A number of well known HRQoL instruments have included questions regarding functional status e.g. the SF-36, and the activity domain of the SGRQ. More recently, the literature has reported a strong correlation between functional exercise capacity and

activities of daily life in people with COPD (Pitta et al., 2005). This would suggest that functional status is a determinant of well being, as expressed as HRQoL.

Despite the recognition of barriers to functional activity in COPD, there are surprisingly few reports of the daily activity patterns of people with COPD in the outpatient setting. The literature recently reported one study that evaluated daily activity in people with COPD, when compared to a control group (Sandland, Singh, Curcio, Jones, & Morgan, 2005). The Sandland study reported COPD participants were 49% less active than a matched control group. COPD participants who required long-term oxygen therapy were 79% less active than their control group. One of the ambitions of a pulmonary rehabilitation program is an increase in domestic functional activity (Singh & Morgan, 2001). Whilst interventions such as pulmonary rehabilitation aim to increase functional capacity, it remains unknown whether this translates to increased functional activity in the participant's environment (Garcia-Aymerich et al., 2004). There have been some reports in the literature examining improvements in tests of functional capacity following participation in an intervention accompanied by no change in functional activity in people with COPD (Behnke, Wewel, Kirsten, Jorres, & Magnussen, 2005; Coronado et al., 2003). In contrast, functional capacity was evaluated in a comparative study between COPD and healthy subjects (Pitta et al., 2005). In this study, the participant's daily activity was compared with the results of a timed walking test. These researchers identified a significant relationship between daily activity and performance in a timed walking test ($r = 0.76$, $P<0.0001$), which was a finding consistent with an earlier report (Haggerty, Stockdale-Woolley, & ZuWallack, 1999). These reports support the notion that dual measures of function at daily performance, and functional capacity levels need to be reported if health interventions aimed at behaviour change are to be genuinely evaluated. Outcomes that measure both functional capacity and performance provide some indication of the degree of disability, as well as enabling the evaluation of the participant's response to treatment following participation in a health intervention (Lareau et al., 1996; Pashkow, 1995).

2.3.2.1 Functional Capacity.

Functional capacity may be determined in a number of ways. The 'gold standard' is the measurement of maximum oxygen uptake ($V_{O2\ max}$) during exercise activity. $V_{O2\ max}$ is considered to be an indicator of functional capacity (Singh, Morgan, Hardman, Rowe, & Bardsley, 1994). $V_{O2\ max}$ represents the maximal achievable level of oxidative metabolism involving large muscle groups. However, in clinical testing situations, a clear plateau may not be achievable before symptom limitation of exercise. Consequently, "V_{O2} peak is often used as an estimate for $V_{O2\ max.}$" (ATS / ACCP, 2003 ,p.229). V_{O2} peak describes the maximum oxygen uptake (aerobic capacity) achievable. In addition to laboratory tests, there are field tests of functional capacity that may be performed in the clinical setting.

Field Tests require few resources and less technical expertise than laboratory conducted investigations of $V_{O2\ max}$. A field test may constitute climbing stairs or walking. The most common field tests reported are walking tests. A walking test can be considered an apt field test for those with moderate to severe cardiovascular compromise; as many with mild cardiovascular conditions may not experience symptoms that limit their mobility (Steele, 1996). Walking is an activity that most people perform on a daily basis (Solway, Brooks, Lacasse, & Thomas, 2001). Due to familiarity, walking may be preferred as an assessment task over cycling or treadmill activity (Singh, Morgan, Scott, Walters, & Hardman, 1992; Solway et al., 2001). Conversely, the inability to be able to walk may be deemed a disability as walking is considered to be a basic functional activity (Ambrosino, 1999; Dyer et al., 2002). In an older population group a walking test is a more reliable functional assessment test than timed chair stands and/or the ability to engage in weight lifting activity (Enright et al., 2003). A Field test should provide a simple and reproducible measure of the individual's functional exercise capacity (Ambrosino, 1999).

Walking tests have been reported to reveal the likely functional activity level experienced at home by the participants which may not be revealed by investigations made with a subject at rest (Singh, 1992; Steele, 1996).

"Resting pulmonary and cardiac function testing cannot reliably predict exercise performance and functional capacity ($V_{O2\ peak}$) in the individual subject with cardiopulmonary disease" (ATS / ACCP, 2003 ,p.214) or the limitations generated by circulatory disease (Ambrosino, 1999). The inclusion of a field test to assess functional capacity provides valuable data to determine overall health status and responsiveness to an intervention in the COPD patient.

Functional status limitations in COPD are usually attributable to reduced respiratory function and deconditioning. However studies reporting the relationship between FEV_1 and exercise ability have revealed a poor correlation (Singh, 1992; Steele, 1996). Some more recent publications have reported otherwise (Casaburi, 2001; Enright et al., 2003).

In addition, there are other variables that may influence walking tests results. The participant's height will influence stride length, and a BMI greater than the normal limits will result in increased energy expenditure and reduce the distance walked (Carter et al., 2003; Enright et al., 2003; Troosters, Gosselink, & Decramer, 1999). Age had been reported as a variable that influences walking ability. Increasing age is associated with a decrease in skeletal muscle mass and strength which have been considered to impact on walking ability (Enright et al., 2003). External factors that have been reported to influence functional capacity in walking tests include the use of walking aids (Solway, Brooks, Lau, & Goldstein, 2002) and environmental conditions (Solway et al., 2001; Steele, 1996).

Walking Tests have been categorised as maximum capacity or endurance tests (Bott & Singh, 1998; Liesker et al., 2002). In a Cochrane Review undertaken on pulmonary rehabilitation the outcomes from these two categories were studied independently as each seeks to measure different constructs with only a moderate correlation between the two (r = 0.52 - 0.81) (Lacasse, Goldstein et al., 2002). A maximum capacity test is one that seeks to measure V_{O2} max/peak in the participants. The outcomes from maximal capacity exercise tests "can be expressed in terms of workload, energy or oxygen consumption" (Lacasse, Goldstein et al., 2002 ,p.3). There currently exist a number of well-

known and validated walking tests. A systematic review of walking tests utilized with COPD patients has been reported in the literature (Solway et al., 2001). Timed (i.e. 12, 6 and 2 minute) walking tests along with the Incremental Shuttle Walk Test (ISWT) are tests that relate to V_{O2} peak (Ambrosino, 1999). However, the timed tests are self pacing, and also share endurance traits (Bott & Singh, 1998; Liesker et al., 2002). Endurance tests seek to measure sub maximal ability over the duration, in an attempt to mimic normal capacity in the participants. Examples of endurance tests include The Endurance Shuttle Walk Test (ESWT) or a timed test (Revill, Morgan, Singh, Williams, & Hardman, 1999). Most activities of daily living (ADL's) are considered to be undertaken at sub maximal capacity. Endurance field tests would gauge the level of functional disability experienced by the COPD participants in their home environment. However, an endurance-walking test has a reported number of disadvantages. These include allowing the subject to self pace their performance according to the time they are required to walk in the test (Steele, 1996) or, results skewed by psychological traits such as motivation (Ambrosino, 1999) or, environmental conditions such as encouragement (Dyer et al., 2002; Guyatt et al., 1984; Steele, 1996).

The Incremental Shuttle Walking Test (ISWT) (Singh et al., 1992), is a symptom limited maximal capacity performance test. The ISWT requires participants to walk (shuttle) back and forth over a 10 metre course rounding a cone 0.5 metres from each end of the course way ("X"). Figure 2.4 depicts an outline of how this test is performed.

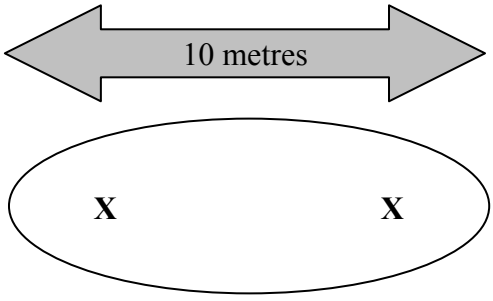


Figure 2.4: The ISWT: (Singh,1992 ,p.1020)

The speed required to undertake this test is determined by an external source: an audio beep from a cassette/compact disc player with the timing between each beep increasing in frequency with each minute by 0.17 metres/second. The speed as dictated by an external source, reduces the supervisor's influence on the subject's performance or, the subject's ability to self-pace to last the distance. This standardised test enables intra and inter subject comparisons (Singh, 1992). There are twelve levels in this walking test, and the number of shuttles increases within each level (Singh, 1992) as tabled: 2.2.

Table 2.2: The ISWT protocol: (Adapted from Singh.1992 ,p.1020)

Level	Shuttles per level	Cumulative total	Metres/sec	Km/hr
1	3	3	0.50	1.8
2	4	7	0.67	2.4
3	5	12	0.84	3
4	6	18	1.01	3.6
5	7	25	1.18	4.2
6	8	33	1.35	4.9
7	9	42	1.52	5.5
8	10	52	1.69	6
9	11	63	1.86	6.7
10	12	75	2.03	7.3
11	13	88	2.20	7.9
12	14	102	2.37	8.5

The incremental nature of the ISWT requires a graduated increase in physical effort. The co-existence of COPD with cardiac pathology in many patients supports the utility of the ISWT as a safe field test than a timed walking test (Steele, 1996). The test endpoints include insufficient acceleration as indicated by being greater than half of one metre away from the cone at the time of the next audio signal, too dyspneic or exhausted to continue, or attainment of 85% of the predicted maximal heart rate.

The ISWT is therefore a field test with a number of distinct advantages. There have been reports of a strong correlation betweenV_{O2max} and the ISWT (r=0.81), and V_{O2max} and a treadmill ISWT (r = 0.88) (Singh et al., 1994). In a comparison of outcomes in COPD subjects who underwent the ISWT and the six minute walk test (6MWT), the distance walked in the 6MWT was greater but, heart rates and dyspnoea as measured on the Borg Scale were greater in the ISWT (Singh, 1992). Both the 6MWT and the ISWT appear to be sensitive enough to detect change as a consequence of attendance at a rehabilitation program (Bott & Singh, 1998).

It had been reported that there remains uncertainty in the literature of the need to evaluate maximal as compared to functional activity levels on health outcomes (Bassett, 2000). The next section reports on another aspect of functional status, functional performance.

2.3.2.2 Functional Performance.

The measurement of functional activity over the duration of an intervention can assess program adherence and measure behavioural change. Log books and exercise diaries are favoured for ease of administration (Tudor-Locke & Myers, 2001), but may be problematic in participants with limited literacy. Furthermore, retrospective recall of low to moderate levels of functional activity have been reported as less than reliable (Bassett, 2000; Belza et al., 2001; Follick, Ahern, & Laser-Wolston, 1984), and limited by the lack of standardized methods in data collection (Dishman, Sallis, & Orenstein, 1985). Objective measures of functional activity include the use of accelerometers and pedometers. The literature has reported a moderate correlation (r = 0.80 – 0.90) between these two methods in measuring functional performance (Bassett, 2000). Pedometers are the less expensive objective measure, therefore their utility is reviewed.

Pedometers can record distance, steps and calories. Most studies report the distance walked in steps as this is the most direct representation of what the pedometer measures (Crouter, Schneider, Karabulut, & Bassett, 2003).

Distance walked in kilometres or miles had been reported as a secondary measurement that requires stride length to be input into the memory (Tudor-Locke & Myers, 2001). The inclusion of stride length should reduces artefact in recordings (Crouter et al., 2003; Tudor-Locke & Myers, 2001). Dual measures of functional performance should enable a comparison between groups and studies with greater accuracy. Therefore, in this project all participants had both distance and steps recorded.

A pedometer is usually worn as a belt mounted device. However, investigations have suggested that the optimal site of attachment remains unknown (Schneider, Crouter, & Bassett, 2004; Swartz, Bassett, Moore, Thompson, & Strath, 2003; Tudor-Locke & Myers, 2001). The mechanism of activation of a pedometer is simple and robust. During ambulation, the vertical movement of the hip triggers the horizontal spring suspended arm in the pedometer which, activates the electrical circuit, and a step is then recorded (Bassett, 2000). Pedometers hold a number of advantages as they are an unobtrusive, accurate and an objective method of quantifying both low level, and incremental functional performance (Bassett, 2000; Belza et al., 2001; Tudor-Locke & Bassett, 2004a; Tudor-Locke & Myers, 2001). In the clinical setting, pedometers are an inexpensive adjunct with little technical nous required for use.

Pedometers have limitations. There have been reports of a failure to record ambulation in participants with a slow walking pace (i.e.<0.9 $m.s^{-1}$) (Bassett, 2000; Crouter et al., 2003; Cyarto, Myers, & Tudor-Locke, 2004; Le Masurier & Tudor-Locke, 2003). An inverse relationship between BMI and accuracy had been reported (Melanson et al., 2004; Tudor-Locke & Bassett, 2004a), and refuted (Swartz et al., 2003). Pedometers had been reported to be limited by their ability to fall off subjects with large girths or, whilst bending (Tudor-Locke & Myers, 2001), and some models have clicked over with motor vehicle activity (Schonhofer et al., 1997). Pedometers are also limited to recording, lower limb activity (Singh & Morgan, 2001). Further limitations that have been reported include the inability of a pedometer to differentiate

between the frequency, intensity or, duration of the ambulatory activity (Bassett, 2000; Tudor-Locke & Bassett, 2004a).

A person's level of weekday and weekend functional activity varies (Trost, Pate et al., 2002). To accurately measure functional activity levels, consecutive, all day recordings, over a seven day period are necessary (Trost, Pate, Freedson, Sallis, & Taylor, 2000; Tudor-Locke & Myers, 2001). In sedentary COPD populations it has been reported that little variation was evidenced in the sample's activity pattern and therefore even less monitoring was required (Tudor-Locke & Myers, 2001). However, an effective health intervention is one that alters the underlying determinants of physical activity (Trost, Owen, Bauman, Sallis, & Brown, 2002). To capture this change in functional performance, an alternative strategy would be to apply pedometers for the duration of the intervention (Tudor-Locke & Myers, 2001). In this project, participants wore their pedometer for the duration of the six-week intervention.

International and national guidelines recommend individuals undertake at least 30 minutes of moderate functional activity on most days of the week (ACSM, 2000b; NHF, 2001; Pate et al., 1995). The literature has reported investigations that have tried to articulate this message into steps per day. The catch cry of Japanese walking clubs of the 1960s was that 10,000 steps per day equated to sufficient ambulation in adults (Tudor-Locke & Bassett, 2004b). In a small study (n=52 healthy volunteers), 8000 steps per day equated to 33 minutes of activity (Tudor-Locke, Ainsworth, Thompson, & Matthews, 2002) and thus, met the guidelines for ambulatory activity. A comparative study of pedometers with treadmill activity in sedentary older women (n=111) found that the equivalent of 50% V_{O2} peak in treadmill walking correlated to 5500 steps per day (Jordan, Jurca, Locke, Church, & Blair, 2005). In the chronically ill normative values have not been reported. However, researchers in the field have speculated that 3500 to 5500 steps per day is likely to be the normative value range (Tudor-Locke & Myers, 2001). Despite the preoccupation with steps per day**,** there is no evidence that a minimum number of steps per day is associated with a reduction in mortality (Tudor-Locke &

Bassett, 2004b). The availability of a benchmark for normative values would distinguish between responders and non-responders in health interventions, and enable cross study comparisons of trends in physical activity over time. The next section reviews the additional ambitions behind interventions applied in COPD; symptom management and HRQoL.

2.4 Ambitions of adjuvant therapies in COPD

2.4.1 Symptom Control

Symptom control is a vital skill that needs to be learnt, and practised in order to live confidently with a chronic condition. Wheezing, cough, sputum production and dyspnoea are amongst the most commonly reported respiratory symptoms associated with COPD. The overlap between bronchitis, asthma and emphysema, was reported in section 1.1. It has been reported in the literature that it is not uncommon for people with obstructive lung disease to share the traits of more than one of these overlapping conditions (Soriano et al., 2003). The dominant symptom, is usually indicative of the underlying condition (Leidy, 1995).

2.4.1.1 Dyspnoea.

Dyspnoea is the cardinal symptom of respiratory disability but, a poor guide to respiratory disease severity (Abramson et al., 1996; Nici et al., 2006). Dyspnoea is not a disease specific symptom, and may be experienced in other health conditions. Phraseology to describe this symptom by people with COPD has been identified as relating to the effort of breathing (Hill, Jenkins, Hillman, & Eastwood, 2004; Jones, 2000). In 1998, the ATS defined dyspnoea as a subjective occurrence of respiratory discomfort that consists of breathing sensations that vary in intensity and are influenced by physiological, psychological, social, and environmental factors (ATS, 1999a). COPD generates increased ventilatory demand (Hess et al., 2002; Mahler &

Horowitz, 1994), reduced respiratory muscle strength (Killian, 1985), and ventilatory impedance generated by hyperinflation (Ambrosino & Scano, 2001). These mechanical disadvantages all contribute to the development of dyspnoea (see section 2.1). Cerebral processes thought to be involved in the perception of dyspnoea include the brain stem, cerebral cortex, and cognitive function (Jones, 2000). Epidemiological studies have reported a strong association between an increased perception of dyspnoea with anxiety, anger, depression and cognitive disturbance (Dales, Spitzer, Schechter, & Suissa, 1989).

The onset of dyspnoea may be a gradual occurrence mitigated by aging and reduced sensory awareness. Individuals may also adapt to their symptoms which will influence their perception of dyspnoea (Boezen, Rijcken, Schouten, & Postma, 1998). The nature of the relationship between dyspnoea and spirometry is unclear (Boezen et al., 1998) highlighted by the fact that the perception of dyspnoea can vary between people with the same spirometry readings (Mahler, Weinberg, Wells, & Feinstein, 1984; Nishmura, Izumi, Tsukino, & Oga, 2002; Wolkove, Dajczman, Colacone, & Kreisman, 1989). One longitudinal study reported no association between deteriorating lung function and worsening dyspnoea (Lareau, Meek, Press, Anholm, & Roos, 1999). These outcomes support the notion that the perception of dyspnoea arises due to the interplay of a multitude of poorly understood mechanisms.

Dyspnoea limits functional exercise tolerance and participation in activities of daily living (ADLs) in people with respiratory disease (Guyatt, Berman, Townsend, & Taylor, 1985; Horowitz, Littenberg, & Mahler, 1996; Mahler & Horowitz, 1994; Woo, 2000). In contrast, there have been some researchers who could not report a correlation between dyspnoea and exercise tolerance in pre-post test studies (Steele, 1996). However, the negative spiral of activity limitation, de-conditioning and loss of enjoyment and participation in life attributed to dyspnoea had been identified in the literature (Meek & Lareau, 2003; Wigal, Creer, & Kotses, 1991).

Dyspnoea is considered to be the primary reason for patients being referred to a pulmonary rehabilitation program (Ambrosino & Scano, 2001). Pulmonary

rehabilitation had been recognized as an effective treatment to break the vicious dyspnoea/inactivity spiral (ATS, 1999c). Figure 2.5 depicts this association.

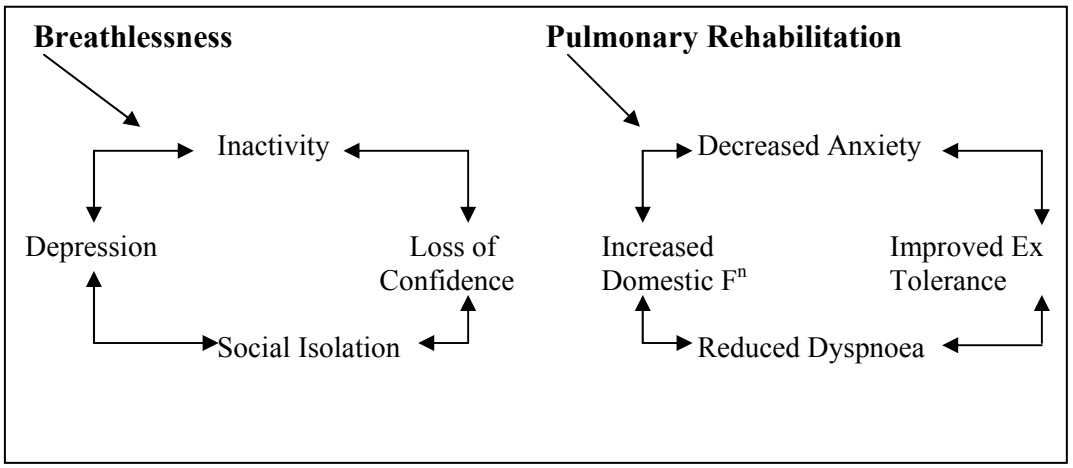


Figure 2.5: The spiral of dyspnoea in COPD: (Webber, 1998 ,p.372).

One small prospective study in pulmonary rehabilitation, has identified that improved symptom management and self-efficacy reduces dyspnoea (Scherer & Schmieder, 1997). Randomised controlled trials with short term follow-up, have demonstrated exercise training as effective in reducing the perception of dyspnoea, via exposure to the symptom in a controlled environment e.g rehabilitation program (Carrieri-Kohlman, Gormley, Douglas, Paul, & Stulbarg, 1996; Lake, Henderson, Briffa, Openshaw, & Musk, 1990). In the past, randomised controlled trials of symptom management alone were unable to demonstrate improved health outcomes beyond usual care (Sassi-Dambron, Eakin, Ries, & Kaplan, 1995). In more recent times, one randomised controlled trial has reported the efficacy of a didactic 'dyspnoea self-management program' that conferred greater effect in the short term than either a combined dyspnoea self-management program with an exercise program (Carrieri-Kohlman et al., 2005). This study suggests that the utility of self-management programs to improve symptom management, and the duration of exercise programs, in the reduction of the perception of dyspnoea, is still unclear.

The degree of dyspnoea reported by the COPD patient has been shown to correlate with mortality rates, disease progression (Hess et al., 2002; Nishmura et al., 2002), and is considered to be an indicator of general health status (Ambrosino & Scano, 2001). Cross sectional studies have reported a negative correlation between the severity of dyspnoea experienced and perceived HRQoL (Ferrer et al., 1997; Hajiro et al., 1998b; Hajiro et al., 1999). Dyspnoea is a significant symptom that affects functional status and HRQoL. Therefore, it is frequently measured with exercise testing, functional daily activities, as a component of HRQoL (Hajiro et al., 1998a) and as a predictor of lung function, disease progression and health outcomes (Nishmura et al., 2002).

2.4.1.1.1 THE EVALUATION OF DYSPNOEA

Dyspnoea may be measured by direct and indirect measures (Hajiro et al., 1998a; Jones, 2000; Nici et al., 2006). The Borg Scale (Borg, 1982) is used during an exercise activity and has been identified as a direct measure of dyspnoea (Hajiro et al., 1998a). The advantages of direct measures include real time quantification of dyspnoea, applied under standard test conditions (Jones, 2000). A review of the Borg's utility, as a direct measure with exercise testing has been reported in the methods section of this thesis as it was included as an adjunct measure with the exercise tests undertaken in this project.

Indirect measures of dyspnoea, require participants to reflect on their level of dyspnoea in daily life and functional activity. Indirect measures are commonly used to measure response to treatment (Jones, 2000). Indirect dyspnoea measures have been reported in cross sectional studies to correlate with HRQoL questionnaires ($r = 0.31 – 0.48$) such as the St George Respiratory Questionnaire (Hajiro et al., 1998a).

This project has elected to simply concentrate on just one dyspnoea outcome measure, the British Medical Research Council's (MRC) Dyspnoea scale. The properties of this scale have been summarized in Chapter Four of this thesis.

2.4.1.2 Mood status.

The irreversible nature of chronic health conditions such as COPD can give rise to a mood disorder such as anxiety or depression. Mood status has been reported in the literature as an affective symptom (Anderson & Burckhardt, 1999). Psychological symptoms often associated with COPD are anxiety, depression and irritability (ATS, 2002; Garvey, 1998).

The literature has reported that depression is a term used to define a disorder rather than a temporarily flat mood. Major depression, has been clearly defined in the American Psychiatric Association's Diagnostic and Statistical Manual for mental disorders (DSM-IV) (APA, 1994). By definition, depression lasts more than two weeks with patients reporting symptoms of a change in appetite, weight, sleep, psychomotor activity; lethargy; feelings of worthlessness, difficulty concentrating or making decisions or recurrent thoughts, plans or attempts of death or, suicide (APA, 1994).

Depression can sap the ability to cope with and potentiate symptoms such as dyspnoea, reduced functional status, and the emotional sequelae a chronic condition may generate (van Ede, Yzermans, & Brouwer, 1999). Fatigue, sleep and appetite changes are symptoms that may be reported by older adults and by people with depression (Milani & Lavie, 1998). The shared symptoms between respiratory disease and depression may lead to a possible misdiagnosis of depression in people with COPD (Norwood, 2006).

Changes in mood status may be a reactive response to COPD or biological in origin (Cassem, 1990). Activities that involve effort may induce unpleasant symptoms such as dyspnoea, which may in turn elicit feelings of anxiety and panic, in susceptible patients. The prevalence of anxiety in people with COPD has been previously reported to range from 10-15% and is approximately three times the prevalence rate recorded within the general population (Brenes, 2003; Karajgi, Rifkin, Doddi, & Kolli, 1990). One prospective study has reported that anxiety is a greater predictor of unplanned need for hospitalisation with COPD than depression (Gudmundsson et al., 2005). An attempted meta-analysis of interventions to reduce anxiety and panic in people

with COPD has reported that the disparate approaches, absence of theoretical models and in general, paucity of publications limits the ability to identify effective treatments (Rose et al., 2002).

In the clinical setting, patients may present with traits of both anxiety and depression (Zigmond & Snaith, 1983). In an inpatient rehabilitation setting clinical levels of anxiety were identified in 50% of patients, and depression in 28% of patients as measured with The Hospital Anxiety and Depression Scale (Dowson et al., 2001). This report is consistent with an earlier report of the dual presence of these traits (Yohannes, Baldwin, & Connolly, 2000). In an outpatient setting, the dual presence of anxiety and depression has also been identified in COPD patients (Kunik et al., 2005) with, a higher incidence recorded in women (Di Marco et al., 2006). Interestingly, there had been more reports in the literature that have concentrated on depression than anxiety in people with COPD.

A systematic review (van Ede et al., 1999) examining the prevalence of depression in the COPD population identified a high baseline prevalence of depression. However, these selected studies were small with variations in both disease severity and outcome measures, which made comparisons difficult. The prevalence of depression in these COPD studies varied from 6-42% (van Ede et al, 1999). The prevalence of depression based on these reports indicates that depression amongst people with COPD is approximately four times greater than the general population within the USA (Kunik et al., 2005).

A recent synthesis of the most current studies suggest an estimated 25-50% of COPD patients have depression (Norwood, 2006). An Australian epidemiological study (Hawthorne, Cheok, Goldney, & Fisher, 2003) reported the prevalence of major depression in a South Australian sample (N=3010) as 7% which is much less than the prevalence reported in COPD (Van Ede, 1999). In addition, these 7% with major depression, reported reduced quality of life, as measured with the Assessment of Quality of Life (AQoL), and increased use of health care resources ($P<0.01$), as compared to those without depression (Hawthorne, Cheok et al., 2003).

A recent report had postulated that the increased prevalence of depression in COPD patients may be explained by an association between nicotine addiction and/or, cerebral hypoxic induced ischemia and depression (Norwood, 2006). However, a study of the prevalence of anxiety and depression in an outpatient pulmonary rehabilitation program (N=45), found no correlation between hypoxemia, anxiety or depression but, a significant correlation between diffusing capacity (TLCO) (a measured component of respiratory function) and depression ($r = 0.33$, $p<0.5$) (Light et al., 1985). A randomised controlled trial in pulmonary rehabilitation supported these earlier findings and also failed to demonstrate any relationship between hypoxemia and depression (Toshima et al., 1992). Other pathophysiologic causes to explain the prevalence of depression include Pro-inflammatory mediators such as TNF-alpha, cytokines and, oxidative stress (Agusti et al., 2003).

Aspects such as role restriction, the reduced ability to keep pace with others, the possibility of early retirement due to increasing symptoms, social isolation, and the realization that no cure currently exists, are outcomes that may trigger depression in some patients with COPD (Light et al., 1985; Ninot et al., 2002; Toshima et al., 1992). How a person perceives their health and, their control over their health, may influence how they cope. Coping, managing stress and nurturing self-efficacy were areas of review considered by the chronic disease self management team at Stanford University.

The literature that reported the impact of mood on functional status was reported earlier in this chapter. The presence of pre-existing depression, cognitive impairment or, limited literacy, have been identified as factors that influence HRQoL outcomes (Kim et al., 2000; Mishoe & Maclean, 2001). The lack of homogeneity in the depression seen in COPD, suggests both physiological and psychological factors may give rise to depression in people burdened by this condition. Baseline mood status should ideally be screened for in order to eliminate pre-morbid bias in the evaluation of health interventions, in a group widely perceived to experience variation in mood status greater than the population norm.

2.4.1.2.1 EVALUATION OF MOOD

The increased prevalence of anxiety and depression in people with COPD support the utility of measuring both traits (Kunik et al., 2005). Depression may be screened for via "three types of measures: self report questionnaires, checklist based structured interviews and clinical assessment by a psychiatrist" (van Ede et al., 1999 ,p.689). To ascertain the prevalence of depression, and the impact this may have on HRQoL and resource utilisation, an outcome measure to capture these data was included in this project. Many questionnaires that evaluate depression are biased towards activity, sleeping, energy and eating. These areas are all affected by respiratory disease. A mood status questionnaire such as The Hospital Anxiety and Depression Scale (The HAD) has two distinct subscales for both anxiety and depression. The HAD does not include questions about symptoms likely to be found in a physical illness, and may be the more pertinent measure, in the evaluation of treatments (ATS, 1999b; Snaith, 1987). The psychometric properties of The HAD are reported in the methods section of this thesis.

"Disease and impairment affect not just the physical domain of life but also a person's psychological state, level of independence and social relationships" (Orley & Kuyken, 1994 ,p.*v*). The next section will report on quality of life.

2.4.2 Quality of Life

Quality of Life is a broad term that has been refined over time and subject to interpretation by various disciplines and all with interests in the impact interventions may confer on health outcomes. There have been a number of definitions of quality of life. Historically, quality of life was referred to as 'subjective well being' or 'life satisfaction' (Oleson, 1990). The World Health Organization had included in their definition of Quality of Life; "the individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals" (Bowling, 1997 ,p.6). Increasingly, the term Health Related Quality of Life (HRQoL) is now reported in the literature. Definitions of HRQoL have encompassed role

functioning (Hutter & Wurtemberger, 1999), the importance of culture, values, and life goals (Bowling, 1997) and the perceptions of the impact an illness has on one's life (Quirk, Baveystock, Wilson, & Jones, 1991). The definition of HRQoL reported by a nurse (Oleson, 1990), defined HRQoL as the subjective perception of happiness or satisfaction with life in areas of importance to the individual. Literature reviews in this field had reported this definition was aligned with the research in this area (Anderson & Burckhardt, 1999). HRQoL has become an outcome parameter that can place the patient's subjective experience of the disease, its effect and, their satisfaction with their living with a chronic condition, on equal parity with clinical data (Arak-Lukmann, Parna, & Maaroos, 2001; Liang, Lew, Stucki, Fortin, & Daltroy, 2002; Martinez et al., 2000; Sturm et al., 2002; Wijnhoven, Kriegsman, Hesselink, Penninx , & de Haan, 2001).

The utility in measuring HRQoL as a component in program evaluation has been identified in the literature. It is possible that two patients with similar clinical profiles may have dramatically different responses, to how they regard their health (Arak-Lukmann et al., 2001). HRQoL has become an outcome examined with increasing interest by clinicians and researchers in areas such as COPD, chronic heart failure, cancer, arthritis and other chronic health conditions due to the increasing prevalence of these health conditions. A search of the CINAHL database of the term HRQoL from 1997-2002 yielded 494 publications. A CINAHL search of the term HRQoL from 1966-1996 yielded zero publications. HRQoL has become a measure utilised to assess both the disease burden, and as a means of evaluating how effective a treatment schedule is in disease management (Harper & Lyles, 1988; Jones, 2002; Juenger et al., 2002; Mahler & Mackowiak, 1995; Martinez et al., 2000).

In a pulmonary rehabilitation Cochrane Review (2003) eleven randomised controlled trials included HRQoL as an outcome measure; (Bendstrup, Ingemann Jensen, Holm, & Bengtsson, 1997; Cambach, Chadwick-Straver, Wagenaar, van Keimpema, & Kemper, 1997; Goldstein, Gort, Stubbing, Avendano, & Guyatt, 1994; Griffiths, Burr, & Campbell, 2000; Lake et al.,

1990; Ries, Kaplan, Limberg, & Prewitt, 1995; Ringbaek et al., 2000; Sassi-Dambron et al., 1995; Simpson, Killian, McCartney, Stubbing, & Jones, 1992; Wijkstra et al., 1994; Wijkstra et al., 1996). Nine of these trials were able to report a statistically significant improvement in HRQoL in participants following participation in an exercised based pulmonary rehabilitation program (PRP).

Demographic variables have also been examined in the respiratory literature to evaluate any association with HRQoL. It has been recognised that most of the HRQoL data in COPD has been studied in men (Foy, Bejeski, Berry, Zaccaro, & Woodward, 2001; Katsura, Yamada, Wakabayashi, & Kida, 2007). This unintentional bias has been previously identified in the literature due to a historically greater prevalence of COPD in men (Domingo-Salvany et al., 2002). However, this creates a void in understanding whether interventions that aim to improve quality of life perform equally with both sexes (Katsura et al., 2007). The literature reports of a randomised controlled trial that have investigated the effect of gender on HRQoL following participation in a short term as compared to an extended pulmonary rehabilitation study (Foy et al., 2001) remain limited. The Foy study reported that all participants significantly improved their report of HRQoL at 3 months ($P<0.01$). However, men were the only group to significantly gain in HRQoL ($P<0.05$) from an extended pulmonary rehabilitation program. The outcomes from this study suggest that the evaluation of health interventions in people with COPD need to be additionally examined for the moderating effect of gender on outcomes.

Marital status has been examined in the literature as a possible mediator of HRQoL outcomes. People with COPD who are married are reported to enjoy greater longevity (Almagro et al., 2002; Rogers, 2000). This could be construed that a spouse would care for the chronically ill partner at home, which in turn may confer enhanced HRQoL. However, in a study to investigate if people nursed at home with COPD had improved HRQoL no such association could be found (Ketelaars et al., 1998).

Smoking status has been identified in the literature as an impediment to optimal HRQoL because smokers report more respiratory symptoms than non-

smokers. The reporting of respiratory symptoms had been identified as inversely proportional to HRQoL and longevity (Ekman, Fagerberg, & Lundman, 2002; Hajiro et al., 1999; Heijdra, Pinto-Plata, Kenney, Rassulo, & Celli, 2002; Jones, 1995; Nishmura et al., 2002; Selim et al., 1997; Tsukino et al., 1996; Wijnhoven et al., 2001).

There is some evidence in the literature to suggest that the measure of HRQoL in a COPD sample is directly proportional to clinical status and inversely proportional to the use of health care resources (Alemayehu, Aubert, Feifer, & Paul, 2002; Fan, Curtis, Tu, McDonell, & Fihn, 2002; Osman, Godden, Friend, Legge, & Douglas, 1997). Clinical trials have reported a significant relationship between HRQoL and mortality (Oga, Nishimura, Tsukino, Sato, & Hajiro, 2003; Ries, Kaplan, Robert, Limberg, & Prewitt, 1995) and conversely, others have found no association (Gerardi et al., 1996). In addition, the literature has reported that perceived HRQoL was independent of the presence of co-morbidities, yet significantly associated with mortality rates (Domingo-Salvany et al., 2002). This finding confirms that HRQoL is an important predictor of health outcomes.

HRQoL is an important measure as it quantifies the disease impact on daily functioning in a formal and standardised manner (Jones, 1995). Clinicians and their patients may interpret outcomes of care differently (Staniszewska, 1999). Particularly as there is a poor correlation between symptoms, functional state and COPD pathology (Guyatt, 1997). Therefore, HRQoL ideally should be viewed as a complementary measure, a parameter to assess outcomes as one of a battery of instruments (Kiebzak, Pierson, Campbell, & Cook, 2002; Mahler & Mackowiak, 1995). The literature has suggested that HRQoL needs to be measured in longitudinal studies i.e. beyond a six-month time frame (Martinez et al., 2000). The burden of a chronic condition needs to be investigated over the duration, as the trajectory of a chronic condition varies over time, and with health status (Belazi, 2002; Mishoe & Maclean, 2001; Testa & Simonson, 1996).

2.4.2.1 HRQoL as an outcome measure.

HRQoL outcome measures require the patient's engagement in order to measure the magnitude of the effect. Tools that facilitate patient involvement shift the attention from the physiological components of the condition to the human concerns (Liang et al., 2002). Yet, the measurement of HRQoL still attracts some criticism. In all of the well known, published and validated HRQOL tools in use, none ask the patient what their expectations are (Staniszewska, 1999). In a similar critique of HRQoL measures, the emphasis on handicap was identified as a drawback in questionnaire design (Hawthorne, Richardson, & Osborne, 1999). These shortcomings are acknowledged in this literature review but, there is sufficient evidence to support the inclusion of HRQoL as an outcome measure in COPD evaluations.

There are a number of instruments that have been used to measure HRQoL. A generic HRQoL questionnaire is considered sensitive for mild to moderate disease states. Beyond this level, a disease specific instrument had been reported to be more sensitive (Tsukino et al., 1996). Generic measurements are multi-dimensional and enable comparison of HRQoL between conditions and, populations and as a means to evaluate health care delivery (Boueri, Bucher-Bartelson, Glenn, & Make, 2001; Harper et al., 1997; Sturm et al., 2002; Testa & Simonson, 1996). Generic HRQoL instruments include the EuroQol (European Quality of life instrument). However, this measure has been reported to be less sensitive in mild symptom disease states (Brazier, Jones, & Kind, 1993). In contrast, the Assessment of Quality of Life questionnaire (AQoL) was developed in Australia (Hawthorne et al., 1999). The AQoL instrument was reported as more sensitive than the SF-36 in detecting change in all dimensions of health except in the area of pain that the SF-36 measures (Osborne, Hawthorne, Lew, & Gray, 2003). The AQoL questionnaire was scaled using multi-attribute theory and can be used in cost utility evaluations (Osborne et al., 2003). The cost utility analysis reports the client's satisfaction with health states and is reported on later in this section. Due to its advantages, the AQoL was selected as the generic HRQoL

instrument for this project. The psychometric properties of this measure is summarised in the methods section of this thesis.

Disease specific instruments seek to capture the change in the impact of symptoms and activity the therapeutic intervention has on the individual's or group's health state over time (Mishoe & Maclean, 2001; Testa & Simonson, 1996). There are a number of well regarded respiratory specific HRQoL instruments. These include The Sickness Impact Profile, the Chronic Disease Respiratory Questionnaire and the St George Respiratory Questionnaire.

The Sickness Impact Profile (SIP) (Bergner, Bobbitt, Carter, & Gilson, 1981) has had reported use in many respiratory studies. This instrument consists of 136 items and takes 20-30 minutes to complete. The main criticism of this instrument is that whilst it has been a sensitive instrument for those with advanced respiratory conditions, it is not sensitive with mild to moderate respiratory conditions (Jones, Baveystock, & Littlejohns, 1989). The Chronic Respiratory Disease Questionnaire (CRDQ) has had significant use as a disease specific questionnaire (Guyatt, Berman, Townsend, Pugsley, & Chambers, 1987). The CRDQ is a twenty item instrument with four subscales; dyspnoea, fatigue, emotional function and mastery. This instrument is reported to be as widely selected in COPD studies as the St George Respiratory Questionnaire (SGRQ) (Rutten-van Molken, Roos, & Van Noord, 1999). Randomised controlled trials with outpatient based COPD participants have reported that the validity, internal consistency and sensitivity to change with both of these instruments were equivalent (Hajiro et al., 1998b; Rutten-van Molken et al., 1999). Controlled trials that have utilised the SGRQ have demonstrated its sensitivity to change in clinical status and its predictive value in health resource utilization (Osman et al., 1997; Seemungal et al., 1998). The SGRQ was selected as the respiratory specific measure for this project. The properties of the SGRQ are reported in the methods section of this thesis.

2.5 Costs of care

In 2001 - 2002 health expenditure in Australia was estimated at 9.3% ($66.6 billion) of the gross domestic product (AIHW, 2003). This estimate is within a similar range to European health care expenditure at 8% and the USA at 14% of their gross domestic product (Halpin, 2006). The Australian Institute of Health and Welfare (AIHW) report noted that $3397.00 was spent on every resident with more than two thirds of this expenditure funded by the Australian Government. This figure had increased by 0.2% from the previous year (AIHW, 2003). The fractional annual increase in expenditure does not appear to be an enormous figure until it is translated into actual monetary costs.

Health policy is often evaluated in terms of costs and benefits (Ferrer-i-Carbonell & van Praag, 2002). However, the benefits and costs that arise from health care interventions have been conceded in the literature as not always fiscal (Price, 2001). It has been reported that the pressure to rationalize health care services and to account for additional services continues to grow in the USA and Europe (Goldstein, Gort, Guyatt, & Feeny, 1997) similarly, in other parts of the globe. The pressure to maximise health outcomes from finite resources, compare the relative value of different programs and plan for future resource allocation supports the utility of an economic analysis (Ramsey et al., 2001; Sculpher, 2001).

An economic analysis has been defined as an "analysis that uses analytical techniques to define choices in resource allocation" (Greenhalgh, 1997 ,p.596). Reported indications to undertake an economic analysis include interventions that are not considered to have an effect on mortality but, may confer an effect on physical, social or psychological well being (McKie, Richardson, Singer, & Kuhse, 1998). An economic evaluation is required to report the perspective of the analysis (Price, 2001; Stone, 1998). The perspective could vary from that of the patient or society (Greenhalgh, 1997; Stone, 1998).

The inclusion of an economic analysis as a part of a comprehensive program evaluation has reported advantages. Health services can maximise the benefits of finite resources by comparing alternative interventions by their costs and consequences (Drummond, 1997; Pickard, Wang, Walton, & Lee, 2005). An economic evaluation of health interventions can also assist decision making at the local level to identify effective interventions (Brosnan & Swint, 2001; Stone, 1998). An effective health intervention is reported to be one that is satisfying to both the staff and participants even if limited, in terms of fiscal outcomes (Price, 2001). Professional judgements and ethical considerations are also necessary in the comprehensive evaluation of health interventions.

The limitations of economic evaluations have also been recognised. It has been reported that economic evaluations were a popular means to gain regulatory approval from governing bodies (Sculpher, 2001). Evaluations undertaken for commercial reasons may simply compare their product with a placebo. The use of a placebo rather than comparisons made with usual care can make the conclusions drawn invalid (Dixon, Deverill, Gannon, Brazier, & Haggard, 1999). Economic evaluations have often concentrated on the appraisal of short-term services i.e. interventional costs. The practice of reporting of costs that befall society aka the third party payer and, not the total costs that are additionally incurred by the patient, must impinge on a true account of costs and benefits (Sculpher, 2001). Short term modelling of costs may not necessarily reflect the costs incurred with disease progression and, over the duration (Oostenbrink, Rutten-van Molken, Monz, & FitzGerald, 2005).

Carer strain is often not quantified in economic evaluations despite the significant role, family members may play in the care of the unwell family member and this must be conceded, as a limitation (Phillips & Thompson, 2005). For these reasons, the literature remains largely speculative as to the influence economic evaluations have on health policy (Stone, 1998). Additional limitations of economic evaluations may arise when a new intervention may have greater efficacy than the existing model of care but at greater cost. To restructure finite resources in order to accommodate a new

therapy constitutes a dilemma of an opportunity cost; - benefits that are foregone in order to fund something else (Sculpher, 2001; Stone, 1998). To arrive at valid conclusions in the evaluation of health interventions, economic evaluations should not be appraised independently of the clinical project (Dixon et al., 1999).

2.5.1 The measurement of costs and benefits

Health in the context of an economic evaluation is regarded as a basic utility in addition to other utilities, such as food and shelter (Brosnan & Swint, 2001). There are a number of forms of economic evaluations; a cost utility analysis (CUA) is one method. In a CUA, the costs of the interventions are summed and the calculation of the quality of life years is the end point in the analysis (Drummond, 1997).

The calculation of the quality of life years is underscored by a basic premise that a patient will trade a certain amount of resources for a health intervention if it leads to improved health (Brosnan & Swint, 2001). In a CUA the patient's state of health is awarded a utility value, on a continuum between 1.0 (perfect health) through to 0 (death) and a negative score is possible, if the state of health is reported to be worse than death (Testa & Simonson, 1996). The utility value generated is a single number that represents the patient's health state preference, and as such is a HRQoL assessment (Petrou, 2005; Testa & Simonson, 1996). The utility value can be elicited via a number of preference methods such as standard gambles, time trade offs or ratings scales (Elnitsky & Stone, 2005; Hawthorne, Richardson, & Day, 1997; McGregor, 2003; Stone, 1998). The time trade off method assumes people are prepared to trade quantity for quality of life and is reported to be one of the better methods of calculating utility weights (Arnesen & Trommald, 2004). In recent times, a report of time trade off weights across a number of health conditions reported a Pearson's correlation of just 0.26 between the severity of the health conditions and perceived HRQoL (Arnesen & Trommald, 2004). This finding again of a poor correlation between objective measures of disease

severity and perceived HRQoL suggests that it may be possible to improve perceived health without a measurable change in health status.

The methods of calculating the health preference weights (utilities), have been readily reported (Elnitsky & Stone, 2005; Petrou, 2005; Testa & Simonson, 1996). HRQoL questionnaires are a popular means of eliciting utility values for a CUA. Generic HRQoL questionnaires such as the EuroQol/ EQoL5D (Dolan, 1997), the SF-36/ SF6D (Brazier, Harper, & Thomas, 1998) and the AQoL (Hawthorne et al., 1997) may be re-coded to health preference (utilities) measures. These utility measures have had reported use in economic analysis in health (Borg et al., 2004; Griffiths, Phillips, Davies, Burr, & Campbell, 2001; Osborne et al., 2003). Generic HRQoL measures represent broad population (societal) values, across a number of health conditions, which have been seen as an asset to comprehensive program evaluations (Elnitsky & Stone, 2005; Sander et al., 2005). To accurately reflect a third party payer perspective, the utility weights should be derived from community preferences for health states and not just represent those of patients or clinicians (Stone, 1998). In addition, the literature has conceded that HRQoL may be valued differently between countries (Pickard et al., 2005). The AQoL is an Australian utility measure calculated via the time trade off method derived from community and patient preferences for health states and was therefore used in this project. An outline of the AQoL is reported in the methods section of this thesis.

When utility preferences are multiplied by time spent in that health state, a single unit - the quality adjusted life year (QALY) is derived (Brosnan & Swint, 2001; Elnitsky & Stone, 2005; Gold, Siegel, Russel, & Weinstein, 1996; Greenhalgh, 1997; Hawthorne et al., 1997; McKie et al., 1998; Phillips & Thompson, 2005; Pickard et al., 2005; Rosen et al., 2005; Sander et al., 2005). The QALY can be quantified "by multiplying the preference value for that state with the time the patient is likely to spend in that state" and expressed as a "cost per QALY" (Greenhalgh.1997, p.596). The QALY is a number that reflects the hypothetical trade off individuals place between quantity and quality of remaining years of life (Arnesen & Trommald, 2004;

Hawthorne et al., 1997; Stone, 1998). For example, an intervention group that reports a QALY of 1.0 suggests that the group were not prepared to give up any years of life in exchange for improvements to their health and, a low QALY indicates that respondents would be willing to give up years of future life in exchange for improved health. (McGregor, 2003). A QALY is calculated by the following formula:

$$QALY = U * t$$

where U = utility value of health and t = the time spent in years in that health state. The method to calculate the utility values has been published (Hawthorne et al., 1997) with an electronic version of the algorithm that may be downloaded for use from http://ariel.unimelb.edu.au/chpe/.

Due to the lack of alternatives, the QALY "remains necessary for the evaluation of medical therapies in terms of health gains" (Ferrer, 2002 ,p.721) from the patient's and community's perspectives (Hawthorne, Osborne, & Elliott, 2003). QALYs are considered to be apt outcome measure if the perspective of the analysis is a societal perspective and the quality and quantity of life are important outcomes of the program being evaluated (Petrou, 2005).

Interventions that produce fewer QALYs for a stated cost would be viewed less favourably in resource allocation (Hawthorne et al., 1997; Stone, 1998). Combining the QALY with the cost of the intervention derives the cost utility ratio (R). The cost utility ratio enables a means of comparison between an interventions with a control group, in order to identify inexpensive (low cost per QALY) interventions in a given sample over the same duration (McGregor, 2003; Phillips & Thompson, 2005). The formula for this ratio has been reported as follows:

$$R = \frac{mean\ C_T - mean\ C_c}{mean\ U_T - mean\ U_C} = \frac{\Delta\ mean\ C}{\Delta\ mean\ U}$$

where C = costs, c = control group, U = utility value (in QALYs),
T = Intervention group, Δ = difference (Griffiths et al., 2001).

A cost utility analysis outlines which therapies are being compared and why (Ramsey et al., 2001). There are four possible outcomes in an economic analysis. The cost effectiveness plane depicts these outcomes as follows:

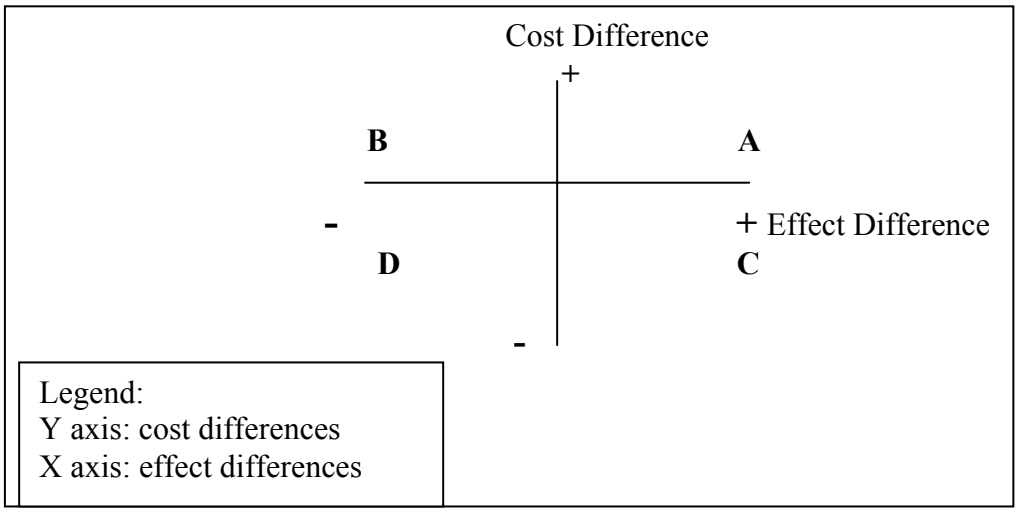


Figure 2.6: Cost effectiveness plane of usual care versus interventions (adapted from Ramsey et al, 2001 ,p. 997).

Quadrant A illustrates the ethical dilemma of an outcome where the intervention is more costly and more effective than usual care. Quadrant B represents an outcome that reports the intervention is less effective and costs more than usual care. Quadrant C is the ideal outcome where the intervention is less costly and more effective than the control/ usual care group. Quadrant D illustrates that the intervention is less costly and less effective than usual care.

Although a course of pulmonary rehabilitation should be considered as part of standard care for people with COPD, demand to access such a program outstrips supply in Melbourne. A competing therapy should be compared against the best standard therapy available prior to the introduction of the new therapy (Ramsey et al., 2001). Therefore in this project, the original aim was to compare the costs and effects of a wait listed (usual care) control group as compared with the intervention groups. Instead, the costs and benefits of pulmonary rehabilitation as compared to pulmonary rehabilitation with the addition of a maintenance program are compared to determine if maintenance therapy conferred added benefits whilst accounting for costs.

The literature has reported that the utility of generic (non monetary) units of measurement e.g. a quality adjusted life year (QALY) should enable comparisons between therapeutic areas (Phillips & Thompson, 2005; Sculpher, 2001) in common units of health related value (Negrin & Vazquez-Polo, 2006). Conversely, comparing QALYs gained by people with a chronic illness in response to an intervention, as compared to an acute illness is reported to be of little value (Arnesen & Trommald, 2004). The concept of a QALY may also be seen to impinge on societal expectations of fair access to health resources (McKie et al., 1998). However, a distinct advantage in a CUA is that the utility value generated by QALYs represents the patient's report of their health and not the assessment made by clinicians or, the general public (Drummond, 1997; Phillips & Thompson, 2005). In the UK the literature has reported that the cost per QALY derived from an intervention is taken into considered by the national institute for clinical excellence (NICE) to enable the calculation of reimbursement by the public purse (Petitti, 2000). In more recent times this notion that a threshold exists for accepting or rejecting a therapy by the cost per QALY was rejected (Halpin, 2006).

Another component of an economic appraisal is a cost effective analysis (CEA). A CEA has been reported in the literature as a subset of a CUA (Stone, 1998). A CEA is an economic evaluation that reports the costs in dollars and, the benefits conferred by health interventions in health units (Luce, Manning, Siegel, & Lipscomb, 1996; Stone, 1998). A CEA requires the inclusion of all resource consumption that affects the decision analysis (Drummond, 1997; Phillips & Thompson, 2005; Stone, 1998). The source of resource valuation needs to be identified to demonstrate how the value was determined. For example, the medicare fee schedule depicts the lowest cost scenario for medical consultations (Schackman, Gold, Stone, & Neumann, 2004). Costs of medications in an economic analysis are frequently valued based on their listed price (Sander et al., 2005).

In addition, with data from different time periods, all data should be valued in comparable terms (Luce et al., 1996). A CEA defines costs at market prices, and reports outcomes stratified as direct, indirect or intangible costs (Stone,

1998). Direct costs are comprised from the medical management of the illness (Sullivan et al., 2000). The medical management costs comprise "the value of goods and services consumed in order to diagnose and manage an illness" as borne by the service and any excess or 'out of pocket' expenses that are paid for by the patient (Crockett, 2002, p.12). A direct cost arises due to an intervention (Stone, 1998) or, due to a change in resource use as a result of an intervention (Brosnan & Swint, 2001). In addition, resource costs also entail opportunity costs. A care givers time in providing home care has also been reported as an example of a direct cost (Luce et al., 1996). Direct benefits from health interventions are considered to be the ability to resume paid employment and avoidance of hospital admissions (Greenhalgh, 1997). Indirect costs are also referred to in the literature as time costs (Phillips & Thompson, 2005). These costs have been reported as "gains or losses due to illness and, overhead costs" (Petitti, 2000 p.184). Staff salaries may be reported as an indirect cost to represent what the service is worth to society (Stone, 1998). Indirect costs account for loss of work and productivity due to illness or premature mortality, in addition to the treatment of co morbid conditions and complications (Crockett et al., 2002; Sullivan et al., 2000).

Indirect costs vary according to disease severity, presence of co-morbidities, gender and carer burden, which has made this outcome difficult to quantify (Crockett et al., 2002; Sullivan et al., 2000). In a CUA, the value of time lost to undertake an intervention by the participant e.g. income loss is considered to be included in the QALY value and is therefore not itemised elsewhere (Brosnan & Swint, 2001). Indirect benefits are deemed to be relief from symptoms, improvement in functional status and a delay in morbidity and mortality (Greenhalgh, 1997).

Intangible costs are often not reported as doubts remains over how to quantify and report this data (Ferrer, 2002). Examples of intangible costs could include the stigma of being diagnosed with a condition, anxiety, pain and suffering (Stephenson, Bauman, Armstrong, Smith, & Bellew, 2000). Changes in health status as measured via generic and disease specific HRQoL instruments provide a means to report intangible costs (Jacobson, Hertzman, Lofdahl,

Skoogh, & Lindgren, 2000). Conversely, intangible benefits have been identified as increased independence and release from sick role behaviour (Greenhalgh, 1997). The limitation of a cost effectiveness evaluation is that unlike a CUA, it does not allow for comparisons to be made between conditions (Stone, 1998). However, a CEA does have merit in determining if an intervention conveys some benefit from its allocated funding. "Cost effectiveness and cost utility analysis are identical except that the effectiveness measure in a cost utility analysis is a measure that reflects societal or individual preferences for the outcomes" (Petitti, 2000 ,p.184).

All economic analysis rely on point estimates and assumptions (Petitti, 2000; Phillips & Thompson, 2005; Stone, 1998). A CEA will often include a sensitivity analysis and discounting of future costs. A sensitivity analysis is undertaken when there is imprecision in the data collection methods (Campbell & Torgerson, 1999). Alternatively, if an underlying assumption in the evaluation should change, a sensitivity analysis can report how sensitive results are to those changes (Briggs, Wonderling, & Mooney, 1997). Uncertainty in costs requires the reporting of confidence intervals (Stone, 1998). A sensitivity analysis comprising upper and lower intervals may be reported with the final figure to support the various assumptions made in the analysis (Mullins, Wang, & Stoller, 2003; Schleinitz & Heidenreich, 2005). Bootstrapping (re-sampling of the sample) is one method to approximate confidence intervals (Stone, 1998). This method enables the calculation of the standard error of measurement. If there is significant uncertainty in the costs and assumptions, the literature suggests the reporting of simulation models (Stone, 1998).

A CEA involves discounting of the future costs and benefits. Discounting allows for people's preference of having something today over the value of having the same thing tomorrow (Campbell & Torgerson, 1999; Phillips & Thompson, 2005). Discounting enables future costs or health outcomes to be discounted to the present value (Drummond, 1997). A 3% discount rate is considered usual practice although as much as a 5% discount has also been reported. Discounting of costs is not undertaken until inflation is included into

the analysis (Brosnan & Swint, 2001). It is not unusual for the opposing factors of discounting and inflation to be equivalent. The discount rate had been regarded in the literature as having minimal impact on outcomes (Sander et al., 2005).

A CEA is designed to rank the efficacy of interventions according to the costs and benefit ratio (Sullivan et al., 2000). Alternatively, with two competing interventions, the incremental cost effectiveness is often reported (Chapman et al., 2003; Goldstein et al., 1997). The incremental cost effectiveness (ICE) has been defined as the "measure of the additional cost of one strategy vs. another compared with the additional effectiveness it delivers" (Gildea, Shermock, Singer, & Stoller, 2003 ,p.1673). The ICE is frequently reported when the implementation of one program is at the expense of funding another. This type of analysis reports whether a particular intervention confers greater benefit as compared to an alternative benefit as compared to no program (Hilleman, 2000; Leigh, Romano, Schenker, & Kreiss, 2002; Oostenbrink et al., 2005; Sullivan et al., 2000). The ICE is usually expressed as the group mean differences. A change in practice that may arise from the implementation of interventions usually requires a cost effectiveness analysis, as health policy is evaluated according to the mean effects and not individual patient outcomes (Greenhalgh 1997). There remains an absence of any economic reports ranking the outcomes of health interventions in COPD by costs and consequences.

2.5.2 Economic studies in COPD

It is well recognised that COPD is a chronic condition with significant societal costs. The distribution of costs are skewed so that the sickest people are often the most expensive patients (Hilleman, 2000). Despite the projected increase in the prevalence of COPD, there are few studies that have reported the economic outcomes from interventions applied in a COPD sample. A Medline and CINAHL search for an economic analysis of COPD has identified few studies. There were reported studies conducted in Canada (Chapman et al., 2003; Goldstein et al., 1997), the USA (Hilleman, 2000; Leigh et al., 2002;

Sullivan et al., 2000; Wilson et al., 2000) and Europe (Jacobson et al., 2000; Miravitlles, Murio, Guerrero, & Gisbert, 2002; Molken, Van Doorslaer, & Rutten, 1992; Troosters, 2000). In a critique of these earlier studies, the majority were in non-controlled, non-randomized trials or, with self selected subjects (Goldstein 1997).

One of the earliest reports of an economic evaluation of COPD, consisted of a review of twenty economic appraisals of both asthma and COPD from the preceding decade (Molken et al., 1992). These authors concluded any information on the cost effectiveness of the use of medications or diagnostic technologies were entirely absent from reporting in respiratory conditions. From 1966 to 1996, only one pulmonary rehabilitation study (Toevs, Kaplan, & Atkins, 1984) reported the costs of the intervention in their analysis. The Toev et al study was limited by no follow up data beyond twelve weeks (Goldstein et al., 1997). Surprisingly, between 1996 and 2002 there were few published COPD studies that had compared their economic outcome data to a control group (Goldstein et al., 1997; Troosters, Gooselink, & Decramer, 2000).

The first reported CUA for pulmonary rehabilitation was a Canadian study that presented society's perspective in the analysis (Goldstein 1997). This randomised study (N=89) compared participation in two months of inpatient rehabilitation with an additional four months of outpatient rehabilitation with usual medical care. The study compared outcomes between groups via a HRQoL measure, the six minute walk test, records of medical appointments, use of community services, prescriptions filled, assistance devices purchased and treatment costs. Indirect costs were not reported as the vast majority of the subjects were retired. Outcome analysis identified that the intervention group improved in HRQoL and walking distance (40 metres). The total costs for the intervention group in Canadian Dollars at six months were CA$12,251 per subject. Total costs for the control group at six months were CA$654 per subject. Ninety per cent of the intervention's costs were associated with the inpatient hospitalisation for rehabilitation. The gains made by the intervention group were maintained at six months. This study's limitations were the

absence of no statistical analysis or, reporting of unplanned admissions to hospital by either the intervention or control group or, why the rate of attrition from the study was so large in the publication of the results.

There has been a report of one randomised controlled trial (n=100) that compared the efficacy of pulmonary rehabilitation to usual medical care with follow up for 18 months (Troosters, 2000). This study reported no significant baseline difference between groups in mortality (p=0.79) or spirometry (p=0.89). The intervention group recorded gains in HRQoL (p=0.002), and exercise tolerance (p=0.01). The intervention costs equated to $2,615 + $625 (mean attendance: 46 + 11 sessions) per participant. The cost of participation was noted to be one third of an inpatient program (Goldstein 1997) and, the benefits were just as significant. The limitations of this study appear to be the reported reimbursement for rehabilitation attendance was the extent of the fiscal analysis.

In a more recent report from the multi national COPD study "Confronting COPD", Chapman (2003) noted the direct and indirect economic impact of COPD to Canadian society. Hospitalisation for an exacerbation of COPD accounted for half of the cost of care. Other studies in COPD have investigated costs of care as classified by disease severity (Hilleman 2000). In the outpatient setting, home oxygen costs have been reported as the most expensive component of care for people living with COPD (Hilleman, 2000; Sullivan et al., 2000).

The analysis of costs of care in COPD to date are somewhat fragmented and it is difficult to draw definite conclusions based on the current literature. The largest cost of care for people with COPD rests with the costs of inpatient admissions. Strategies that delay disease progression and reduce unplanned health care utilization need to be tried and tested. There remains uncertainty whether pulmonary rehabilitation is the most cost effective means of improving HRQoL in COPD (Goldstein, 1997). In addition, new modalities for treatment may demonstrate equal parity in improving HRQoL and/or health resource use for a fraction of the cost of a PRP. Conducted with integrity and attention to detail an economic analysis enables optimal

evaluation of finite resources (Price, 2001). The next section of this chapter summarises the literature that reports on the enabling interventions undertaken in this project.

2.6 Enabling Interventions

The literature reports different approaches to the management of chronic health conditions. There are adjuvant therapies that may have a disease specific focus such as a PRP, whilst other therapies may have a generic health focus e.g. the Stanford model CDSMP. COPD is a chronic condition that frequently co-exists with other chronic disease states (Croxton et al., 2003; Huiart et al., 2005; Schroeder et al., 2003). The CDSMP is an outpatient-based program. The PRP literature review in this section has therefore concentrated on outpatient-based PRPs.

2.6.1 Pulmonary Rehabilitation

Forty years ago, a person presenting with COPD would have been advised to rest and avoid becoming short of breath (Garvey, 1998). Since that time, the idea that exercise offers a means of optimising functional exercise tolerance and symptom control in the COPD patient has gradually become accepted. By 1999, the ATS had endorsed participation in a pulmonary rehabilitation program (PRP) based on published reports that participation in this adjuvant therapy may confer a reduction in impairment, disability, prolong survival, and reduce the health care burden (Cambach et al., 1999). Today, national and international guidelines endorse participation in a PRP (McKenzie et al., 2003; NHLBI / WHO, 2001).

Initially the effectiveness of participation in a PRP was measured by repeated respiratory function tests. There is no evidence that pulmonary rehabilitation could appreciably improve impaired lung function (ACCP / AACVPR, 1997; BTS, 2001; Guyatt, Berman, & Townsend, 1987; Hui & Hewitt, 2003; O'Donnell, McGuire, Lorelei, & Webb, 1998). When considered in the context of other health outcome measures, such as symptom management, functional status and HRQoL, pulmonary rehabilitation programs (PRP) have

been able to demonstrate a benefit on other measures such as HRQoL, and exercise tolerance.

2.6.1.1 Selection criteria to attend Pulmonary Rehabilitation.

PRPs should be made available to all participants who are willing and able to attend (Celli, 1997; Frith, 2002; Nici et al., 2006). There have been reports of PRP studies that have required participants to be reformed smokers (Clini et al., 2001) despite smokers doing just as well as non smokers (Hill, 2006). In a small study that compared attrition from a four-week PRP by smoking status, current smokers were less likely to attend or complete the program (28% vs. 8%, $P<0.02$), than non-smokers (Young, Dewse, Fergusson, & Kolbe, 1999). In the USA, the correlation between smoking with reduced functional status in older people has been identified in the literature (Ostbye, jnr;, Krause, & Van Scoyoc, 2002). Whilst recognising the correlation between impaired mobility or, non PRP completion with smoking status, smokers were not excluded from this study as there were no smoking cessation clinics at Hospital A or B to refer COPD participants to.

The severity of symptoms has been evaluated as a possible criterion for admission to a PRP to evaluate who may benefit (Wedzicha et al., 1998). This randomised controlled trial stratified COPD subjects (N=126) categorised by their grade of dyspnoea as reported via the Medical Research Council (MRC) Dyspnoea scale. Participants who rated their baseline dyspnoea level, as five out of a maximum of five recorded no improvement in this symptom following PRP participation. These researchers therefore recommended that prospective PRP participants be selected on the basis of their reported dyspnoea level. In contrast, a study of the effects of PRP participation (n=151) reported all participants from mild to severe COPD achieved a significant reduction in their perception of dyspnoea post PRP completion (Berry, Rejeski, Adair, & Zaccaro, 1999). Today, the merits of a PRP are recognised and participants selection is not biased towards early responders but, open to all who are willing to attend. However, the basis of program delivery and components still requires further evaluation (Troosters et al., 2005).

2.6.2 Program structure

The frequency, and duration of the program have been identified as significant determinants of the outcomes from pulmonary rehabilitation (Clini et al., 2001). A retrospective audit to assess the effectiveness of a once weekly PRP was reported in Ireland (O'Neill, Johnstonn, Burrell, & MacMahon, 2001). This study was limited to no available evidence of the duration of benefits beyond six-weeks. Therefore, any benefit beyond the short term cannot be determined. A twice weekly PRP has been reported as insufficient to significantly improve exercise tolerance, HRQoL or dyspnoea (Ringbaek et al., 2000). Other studies have demonstrated a statistically significant reduction in the report of dyspnoea (Normandin et al., 2002; Reardon et al., 1994), and a significant improvement in functional exercise tolerance and activities of daily living (Strijbos, Postma, van Altena, Gimeno, & Koeter, 1996; Wijkstra et al., 1994). A twice-weekly supervised PRP has also been reported to lead to a physiological training response in exercise ability (Vogiatzis, Williamson, Miles, & Taylor, 1999).

Other studies have investigated the efficacy of thrice-weekly supervised program sessions. Randomised controlled trials, and prospective cohorts in pulmonary rehabilitation that required thrice weekly attendance were able to demonstrate improved functional capacity (Bendstrup et al., 1997; Cambach et al., 1997; Lake et al., 1990; Rossi et al., 2005), a reduction in dyspnoea (Simpson et al., 1992) and, improved HRQoL (Cambach et al., 1997; Clini et al., 2001; de Torres et al., 2002; Griffiths, Burr, & Campbell, 2000; Rossi et al., 2005). These reports of significant gains would suggest, that attendance at a supervised program would need to be three times a week. However, twice weekly PRP attendance can also confer benefits on participants. This is confirmed by the BTS who have indicated that a twice-weekly supervised program in addition to at least one extra session was needed for sustained improvement in health outcomes (BTS, 2001).

The delivery of a shorter pulmonary rehabilitation program would be a less expensive service to provide. However, no party is served by a program that produces no, or at best, mediocre or, short-lived gains. In recent times, the

uncertainty in the literature of the optimal duration of a PRP has been recognized (Lacasse, Brosseau et al., 2003a). The guidelines suggest that based on randomised controlled studies, an outpatient based PRP should continue for a minimum of six-weeks to ensure long term gains (Abramson, Crockett, Frith, & McDonald, 2006; BTS, 2001).

PRPs have been regarded as having three phases in the continuum of care for people with COPD. The initial program, the transfer of the gains made with improved physical performance, and the third phase of maintenance of the improvements and, reduction in disability (Thomas, 1996). "There is no substantial evidence that prolonged maintenance treatment is beneficial or if it is, what form it should take" (BTS, 2001 ,p.830). The next section highlights the outcomes from maintenance programs (PRP+m) that have been reported in the literature.

The physical benefits of PRP participation will diminish over time when exercise activity is not maintained (Lacasse, Maltais, & Goldstein, 2004; Verrill, Barton, Beasley, & Lippard, 2005). Early reports in the literature concerning PRP participants who have attended a maintenance exercise program suggested that this continuation of therapy might be unnecessary. In a study that reported a twelve month follow up of graduates from a six-week PRP there were no significant differences reported between the non maintenance, and maintenance subjects in walking or HRQoL (Vale, Reardon, & ZuWallack, 1993). In contrast, there are other reports in the literature of long term (12 month) PRPs that demonstrated improved exercise tolerance yet no significant difference in HRQoL (Engstrom, Persson, Larsson, & Sullivan, 1999). More recently, a prospective study examined the utility of a 12 vs. 24 week PRP over a number of health outcomes (Verrill et al., 2005). These clinicians had reported that early gains are recorded and sustained with short term programs but, only measures such as exercise tolerance continued to increase with a longer program. These outcomes lend support for the efficacy of a randomised study with a maintenance program. One Australian study compared maintenance strategies via a randomised trial between a community PRP, and home based PRP; the rate of participants attrition (73%) halted data

analysis beyond three months (Elliott, Watson, Wilkinson, Musk, & Lake, 2004). In an earlier reported study with 12 month follow up, the rate of attrition was reported as 41% (Foglio, 2001). These rates of attrition suggest participants in long-term evaluations became well and discontinued or, could not see the value in the intervention or, the outcome measures.

In a randomised study of enhanced (i.e. telephone follow up) vs. usual care post PRP (n=109), exercise capacity and HRQoL were equivalent between groups and the rate of attrition from exercise was attributed to an exacerbation of COPD (Brooks, Krip, Mangovski-Alzamora, & Goldstein, 2002). Perhaps the attrition rates suggest the fundamental flaw with atheoretical PRPs. Behavioural change is complex and even more difficult to sustain. Based on a summary of the literature, extended programs offer more likelihood of supporting a change in behaviour (Spruit, Troosters, Trappenburg, Decramer, & Gosselink, 2004). Possibly the real challenge for PRP+m is to ensure that once the participants has recovered from their exacerbation they retain their new behaviour and keep exercising.

The progressive nature of COPD and occurrence of exacerbations impacts on the ability to sustain a (new) active lifestyle, and long term maintenance has been speculated as therefore unlikely (Bestall et al., 2003). Other maintenance methods evaluated in the literature have included telephone contact and follow up visits post PRP. These interventions have not been reported as effective exercise maintenance strategies (Brooks et al., 2002; Ries, Kaplan, Myers, & Prewitt, 2003). Questions have remained regarding maintenance program design, frequency, duration and the participant profile that requires such a program. The utility of a short term as compared to a maintenance program has yet to be evaluated via a randomised controlled trial in COPD (ATS, 1999b). One of the tasks set for this project was to explore whether maintenance PRP was a cost effective supplementary therapy.

2.6.3 Program content

The content of comprehensive PRPs is generally comprised of four components: exercise training, adjunct patient education, behavioural interventions and outcome measures (ATS, 1999b). For organisational purposes, these components have been summarised separately.

2.6.3.1 Exercise.

Exercise is the cornerstone to a PRP, due to the frequent reports of dyspnoea and muscle fatigue with COPD (BTS, 2001; Celli, 1997; Frith, 2002). The PRP is designed to reverse the deconditioning and systemic inflammation of COPD on skeletal muscle (Troosters et al., 2005). The reversal of muscle de-conditioning and improved cadence enable PRP participants to walk further for less metabolic effort, dyspnoea, and therefore minimise the disability of COPD (ACCP / AACVPR, 1997; ATS, 1999c). To achieve these outcomes, PRPs are based on the compilation and interaction of the physical conditioning principles of intensity, specificity and reversibility as posited by the American College of Sports Medicine, (ACSM, 2000a). These three principles of physical conditioning as they relate to a PRP, have been briefly summarised.

2.6.3.1.1 INTENSITY

Endurance training at a set intensity or duration, with the duration or intensity increased as tolerated is a common exercise prescription in pulmonary rehabilitation (BTS, 2001). Intensity may be determined via a formula using target heart rate as the dependent variable (ATS, 1999b). Symptom ratings of dyspnoea are an alternative method of guiding exercise intensity. A level of 12 to 15 on Borg's Rate of Perceived Exertion (RPE) 6 to 20 scale, or 4 to 6 on the Borg 0-10 category ratio scale had been reported as sufficient training intensity (ACSM, 1998; Horowitz et al., 1996; Troosters et al., 2005). In a

cardiac rehabilitation program, aerobic exercise and peripheral strength training is pivotal to the exercise plan (Haccoun et al., 2002). Due to reduced expiratory airflow capacity, aerobic exercise was initially discounted as a viable training method for a PRP (ATS & ERS, 1999). However, cardiac output in most subjects with COPD is not a limiting factor to exercise capacity therefore, central training is considered possible (Sietsema, 2001). Ries and colleagues have reported that COPD participants can be safely exercised at near maximal intensity (Ries et al., 1997). Training intensity can be safely commenced from 60-70% of the VO_2 peak derived from the shuttle-walking test (ATS, 1999b). All three methods of determining exercise intensity enable an individualised prescription for client activity (BTS, 2001). Furthermore, training intensity at this level is considered to be above the anaerobic threshold (ATS, 1999b).

2.6.3.1.2.SPECIFICITY

Despite some transfer effect with exercise training, the benefits of PRP participation are usually identified from the muscle groups specifically treated. Lower limb muscle function, is thought to be influenced by hypoxemia, de-conditioning, and oxidative stress (Haccoun et al., 2002). It has been suggested that a lower limb exercise training program, as a part of the clinical management of the COPD patient, may halt the de-conditioning in lower limb muscles, improve functional ability, and dyspnoea generated by exertion (Agusti 2003). The purpose of exercise as an intervention is to improve functional capacity (ATS, 1999b). An increased functional ability had been demonstrated to improve HRQoL, and reduce mortality and morbidity (Durstine, 1997). The reported specificity of the PRP exercise components may be comprised solely or, as a combination of lower limb, upper limb, strength, endurance, and interval training schedules (ACCP / AACVPR, 1997; ATS, 1999b; BTS, 2001; Troosters et al., 2005). Based on a synthesis of the literature in PRP, lower limb exercising is considered mandatory with, the addition of upper limb and strength building exercises as beneficial (BTS, 2001). This project has therefore implemented a lower limb exercise program

with a small component of upper limb free weights strength training as described in the methods chapter.

2.6.3.1.3 REVERSIBILITY

Several studies have evaluated strategies to offset reversibility to or, near baseline functional status following a short PRP. The benefits, conferred by short-term programs has been reported as short lived (Guyatt, Berman, & Townsend, 1987), and also sustained until 12 months (Ries, Kaplan, Limberg et al., 1995; Troosters et al., 2000). Furthermore, the literature has reported limited benefits of repeated short bursts of PRP attendance diminished with time (Foglio, 2001). The benefits conferred from an exercise program in any sample population, healthy or otherwise, generally continue for as long as the exercise activity does.

2.6.3.1.4 THE MAGNITUDE OF BENEFIT

There have been many reports in the literature that have investigated the efficacy of exercise training as a component to a PRP. Randomised controlled trials in PRP have been tabled in Appendix One. These tables highlight the difficulty in making comparisons between studies as there has been much variability in exercise content, and outcome measures. The significant variability and a 'free for all approach' to exercise training in PRPs, must influence outcomes (Cooper, 2001). To gauge the effect size of the benefits participation in a PRP may confer, there have been a few meta-analyses reported in the literature. A meta-analysis of published randomised PRP studies has investigated the effect of PRP participation on HRQoL and exercise capacity (Lacasse, Brosseau, & Milne, 2003). The Lacasse meta analysis was limited to studies that had reported the use of the Chronic Respiratory Disease Questionnaire (CRDQ), and the six-minute walking test. Nine studies had reported improved HRQoL at twice the level of the MCID for this instrument. However, the MCID for the walking test (50 metres) was

not achieved in the ten randomised studies examined. This suggests that participation in a PRP will confer improved HRQoL as compared to usual care, and independent of any functional gains (Lacasse, Brosseau, & Milne, 2003). It has been previously reported that two out of three people with COPD will report some benefit from participation in a PRP (Troosters, Gosselink, & Decramer, 2001). In more recent times, the question remains why such a high proportion of participants do not benefit (Troosters et al., 2005). Other reported meta-analyses in the literature concentrated on evaluating the effect size PRP participation conferred on exercise capacity, and symptoms such as dyspnoea (Salman, Mosier, & Beasley, 2003). The Salman meta- analysis reported a large effect size (*d*= 0.71, 95%CI 0.43 - 0.99) when exercise capacity was evaluated from 20 randomised studies. Interestingly, the control groups measured a reduction in exercise capacity from their baseline by 76%. A reduction in dyspnoea as measured with the CRDQ was equally large in effect from PRP participation (*d*= 0.62, 95% CI 0.26-0.91). Furthermore, the control groups recorded an increase in their report of dyspnoea by 73% (Salman et al., 2003).

The Salman meta-analysis further analysed the effects of PRP participation by exercise strategy; upper/lower limb as compared to inspiratory muscle training. The former group conferred the greatest improvement in exercise capacity and dyspnoea reduction (Salman et al., 2003). This meta-analysis confirms the utility of a lower limb exercise training schedule.

2.6.3.2 Education.

Education in health has frequently been aimed at changing attitudes and behaviour in the belief that it would help reduce morbidity or mortality. The merit of educational sessions as an intervention in pulmonary rehabilitation has been reported as conferring no statistically significant benefit on the program's participants when compared to usual medical care or an exercise group (Albert, 1997; Janelli, Scherer, & Schmieder, 1991; Ries, Kaplan, Limberg et al., 1995; Sassi-Dambron et al., 1995; Scherer, Schmieder, &

Shimmel, 1998). In a meta-analysis of pulmonary rehabilitation studies, an education arm had often been reported to be used in lieu of a control group with, no study able to report equivalent outcomes to an exercise program (Lacasse, Guyatt, & Goldstein, 1997). A review of the reported literature suggests that there is much variability in what constitutes an education program for people with a respiratory condition. Such variability suggests a lack of consensus on the effectiveness of varying educational interventions (Sudre, Jacquemet, Uldry, & Perneger, 1999).

Randomised studies in asthma have also demonstrated didactic education sessions conferred no significant benefit in HRQoL or, health resource utilization when compared to usual medical care (Abdulwadud, Abramson, Forbes, James, & Walters, 1999; Premaratne et al., 1999). In one respiratory study that sought to compare the effect of education and self-management on health care utilization the results were consistent with the need to facilitate efficacious behaviour as a means of achieving improved health management. A prospective controlled study sought to investigate whether an action plan, education or, strategies to facilitate self-capacity had an impact on Emergency Department attendance in an asthmatic population (Cote et al., 2001). The subjects were randomised to (i) control, (ii) education plus action plan or, (iii) education, action plan and strategies to facilitate self-capacity. Outcomes at twelve months identified, only the latter group whose intervention included self-efficacy strategies demonstrated increased knowledge, willingness to manage medications, quality of life and peak expiratory flow improvements. The number of unscheduled medical visits by this latter group was recorded as significantly less ($P = 0.03$). These researchers concluded that people, given insufficient information or reinforcement do not possess enough self-confidence to increase their use of their puffer medication despite peak flow or, symptom severity. This study concluded that an effective method to manage patients with exacerbations or breathing difficulties must include "access to a long and structured educational intervention aimed at improving self efficacy" (Cote 2001 p1418). This study had identified that limited education alone when poorly targeted confers no additional benefit beyond usual medical care. Based on this and similar studies, the utility of a

behavioural model to facilitate optimal outcomes needs to be imbedded in program delivery.

Stanford University's Professor Lorig, a nurse, reported her initial research in chronic disease management included an examination of the conceptual models health education, had until then, been based upon (Lorig & Laurin, 1985). Lorig and Laurin contended that one of the flaws in health education had been the assumption that the same model of education for an acute condition would be applicable to a chronic condition. Lorig had identified that in historical epidemiological and, other studies, a change in behaviour e.g. vaccination, led to a change in health status i.e. improved health (Lorig & Laurin, 1985). However, with chronic conditions a patient requires ongoing commitment to a behavioural change i.e. smoking cessation or exercise adherence which require more effort than a solitary vaccination. In addition, a long term change in behaviour does not necessary result in improved health. In cardiac disease for example, there are risk factors for developing heart disease such as a genetic history, advanced age, and being male that no behavioural change can circumvent. Therefore, how to live confidently with a condition, access and utilise health resources as appropriate would seem a more sensible intervention than increasing the patient's knowledge acumen of the disease.

2.6.3.3 Behavioural Interventions.

In more recent times, the primary goal of a pulmonary rehabilitation program has been simply described as facilitating a change in behaviour from sedentary to active (Troosters et al., 2005). The third reported component to a comprehensive pulmonary rehabilitation program is the concept of a behavioural intervention. The BTS has reported "psychological & behavioural intervention is already embedded in pulmonary rehabilitation programs through the delivery of education, small group discussions and relaxation therapy" (BTS, 2001 ,p.831). The ATS had earlier espoused that the behavioural components of a comprehensive PRP included education sessions,

instruction in progressive muscle relaxation, stress management, panic control and peer support (ATS, 1999b). However, the delivery of education and, relaxation therapy in small groups as the (behavioural) intervention is consistent with an implicit program, or tacit theory. Programs without the underpinning of a developed conceptual model risk becoming operationally ambiguous, and the outcomes can be difficult to interpret. The appraisal of a tacit program risks becoming a 'black box' evaluation as the nature of the program may not be able to explain the outcomes observed, in contrast to programs with an articulated conceptual model drawn from the social sciences (Rossi et al., 2004). The literature had reported that optimisation of the effects of a cardiopulmonary program required an understanding of social learning theory and theories of behavioural change need to be imbedded in the program's practice (Berarducci & Lengacher, 1998).

A pilot study reported a significant effect for psychotherapy alone on improved exercise tolerance in people with moderate to severe COPD (Eiser, West, Evans, Jeffers, & Quirk, 1997). In this randomised controlled trial (n=18), the intervention group recorded a 24% increase in their walking test that was sustained for 12 weeks. However, the small sample size and brief follow-up must be conceded as limiting features to this report.

The role of self efficacy and social support in predicting exercise behaviour has been examined via a randomised controlled trial, in a cardiac rehabilitation program (Carlson et al., 2001). These researchers randomised participants (N=80) to two cardiac rehabilitation programs. One program was a staff mediated program ("usual care") and the alternative was a modified program that emphasised independent exercise and included support meetings. Program follow up continued for six months. The usual care group reported three times greater level of attrition. Furthermore, self-efficacy was found to be a predictor of exercise frequency ($P<0.01$). Ratings of self efficacy, can be valid predictors of health related actions (Berarducci & Lengacher, 1998). It may be concluded that efficacy builders/ a conceptual health model could optimise uptake and maintain the program benefits, once the supervision has stopped. Self Efficacy Theory as outlined by Bandura, proposes that self

efficacious beliefs influence the type of activity people choose to engage in, the level of effort they spend and, their perseverance in the face of difficulty (Bosscher & Smit, 1998).

A small outpatient based PRP study (n=40) (Lox & Freehill, 1999) investigated measures of self-efficacy, exercise status and quality of life. The study's findings revealed an increase in self-efficacy together with an increase in exercise tolerance. Previous studies have identified that COPD patients avoid participating in activities for fear of dyspnoea. This is consistent with Bandura's theory, which suggests that people avoid activities they fear are beyond them (Lox & Freehill, 1999). The Lox & Freehill study therefore suggests that improved self-efficacy is an important outcome and an enabling component that results from participating in a pulmonary rehabilitation program. Hence, behavioural strategies that build on the participant's self-efficacy need to be actively incorporated into programs to generate a lasting effect.

2.6.3.3.1 SELF MANAGEMENT PROGRAMS

Self care involves patients as partners in their own care by maintaining their optimal well being through healthy practices, despite their chronic condition. Self management is more than self care as it involves apt use of relevant professional medical resources (Fries, Lorig, & Holman, 2003). Self management has been defined as any formal program that teaches the skills required to confidently live with a chronic condition, change health behaviours and live a functional life (Bourbeau et al., 2003; Chodosh et al., 2005). Successful self-management involves cognitive decision making, undertaken to manage the symptoms that arise from one's chronic health condition (Riegal 2000). The concept of self-management is not new but has become an increasingly accepted and expected tenet in patient care today (Bodenheimer, 1999). Optimal care today is considered to not only include good medical care but also the provision to improve patients' knowledge and self-management skills (Von Korff, Glascow & Sharpe.2002). Prospective studies with elderly

participants have successfully reported significant improvement in perceived HRQoL and maintenance of independence following participation in self management programs (Nelson et al., 1984). However, despite the acceptance of self management as a necessary model of care, the evidence base to support the utility of self management programs remains remarkably lean (Chodosh et al., 2005). Interestingly, most of the literature that has examined the utility of a self -management program for people with COPD have been disease specific programs rather than with generic self management programs.

2.6.3.3.1.1.Reported self management strategies in COPD

Studies of self-management interventions in COPD have been the subject of a Cochrane Library systematic review (Monninkhof et al., 2003). This review identified nine trials with two to twelve months follow up of self-management practices compared to usual care. Monninkhof's review examined the effect of self-management programs on HRQoL and health care utilization. Generic HRQoL instruments were measures employed in seven trials, and one trial utilized the St George Respiratory Questionnaire (SGRQ). There was some variability in other measures examined; respiratory function testing, hospital admissions and use of medications were additional outcomes selected in some of these trials. None of the studies reported a significant reduction in health care utilization between the intervention and usual care groups. HRQoL measured with a disease specific instrument (SGRQ) demonstrated some improvement in scores post intervention but these did not reach statistical significance. This review concluded that there was insufficient evidence to form any recommendations with respect to the utility of a self-management program in a COPD sample. However, the reported 'self management' trials consisted of didactic education sessions in groups or with individual patients. The 'self management' strategies implemented in these studies consisted of the distribution of pamphlets, or the formation of an emergency action plan in the event of an exacerbation. The apparent absence of a conceptual model that the 'self management' interventions were based on in these trials would appear to have been a limiting feature. The conclusion drawn by Monninkhof

(2003) was to note that a randomised controlled trial designed for people with COPD that focuses on behavioural change as an intervention remains absent. Furthermore, this Cochrane review reported that in all the reported studies applied to a COPD sample, none had evaluated the effect of their self-management model on exercise capacity (Monninkhof et al., 2003).

COPD was reported in chapter one of this thesis as a condition more prevalent with age. The likelihood of older adults reporting two or more chronic conditions had been recognised in the literature (Lorig, Sobel et al., 1999). Instead of disease specific programs, it has been considered by some health researchers that programs which concentrated on the common problems encountered by chronic health issues may be more appropriate (Lorig, Sobel et al., 1999). The next section reports on a generic chronic disease self management program.

2.6.3.3.1.2. The Stanford Model Chronic Disease Self Management Program

The Stanford model Chronic Disease Self Management Program (CDSMP) is a patient-centred generic condition, self-management course. The program content had been reported in Chapter One. The CDSMP is an off shoot of the original Stanford arthritis self management program (ASMP) which has been well reported (Barlow, Turner, & Wright, 2000; Holman, Mazonson, & Lorig, 1989; Lorig, Gonzalez, & Ritter, 1999; Lorig & Holman, 1993; McColl, 2001). One of the limitations identified with the ASMP in both the UK and USA has been that the vast majority of participants, approximately 80% have been women, which may limit the generalisability of the results across both genders (Barlow, Wright, & Lorig, 2001). Statistically significant benefits from ASMP participation have been reported in the literature. However the effect size from program participation on anxiety (d=0.18), and depression (d=0.2) as measured with The HAD, were small (Barlow et al., 2000). This is not an unique finding. Other ASMP's had been subject to scrutiny and statistically significant but, small effect sizes have also been reported (Warsi, LaValley, Wang, Avorn, & Solomon, 2003).

The Stanford model CDSMP includes an overt philosophical underpinning that all chronic conditions generate the same challenges amongst individuals, people can be taught to problem solve which reduces unplanned/ reactive use of medical services. "A positive role model inspires the patient to engage in self management "(Lorig.1999, p.6).

The CDSMP can be facilitated by two health professionals, lay instructors or a combination of health professional and a lay person. The incorporation of a peer as a role model is consistent with social cognitive theory as posited by Bandura; that people learn from a social comparative force (Bandura, 1997b). A research study to compare a lay taught and professionally taught Stanford Model Arthritis self management program reported no statistically significant differences in the program outcomes (Lorig et al., 1986). The delivery of a clinician led as compared with a lay and clinician led CDSMP in Australia, reported equivalent increases in self-efficacy across both groups (Murphy, Campbell, Saunders, Berlowitz, & Jackson, 2004).

It has been difficult to calculate the effect sizes from the reported benefits of participation in the Stanford model CDSMP as the raw data to enable these calculations is absent from the publications. In the domains of interest to this project, statistically significant findings have been reported in functional activity (Lorig & Holman, 1993; Lorig, Sobel et al., 1999). One study reported a significant increase in activity tolerance by 13-16 minutes post program as compared to a control group increase of zero to five minutes ($p<0.01$) (Lorig, Sobel et al., 1999). For a sedentary populace this is not an insignificant behavioural change. Of further interest, in a breakdown of results by clinical condition, participants with lung disease increased their weekly aerobic exercise from baseline by 10% as compared to the lung control group. Furthermore, the lung disease subgroup behaved no differently on outcomes as compared to the group mean or disease specific groups (Lorig & Holman, 1993). This supports the utility of evaluating the efficacy of a generic therapy for people with COPD.

Symptom management has been evaluated in association with the use of the CDSMP by means of a number of instruments. In general, CDSMP

participants have been reported to experience reduced pain and fatigue (Lorig & Holman, 1993), and reduced lethargy (Lorig, Sobel et al., 1999). Furthermore, longitudinal evaluation has reported that at 12 months, program participants recorded a sustained reduction in depression (P<0.001), fatigue (P=0.002), dyspnoea (P=0.003) and health distress (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001). Qualitative case reports have also identified a reduction of symptoms, such as pain in the program graduates (Lorig, Mazonson, & Holman, 1993) In addition, program participants have recorded statistically significant increases in improved relationships with health care professionals and their family (Lorig, Sobel et al., 1999). At 12 months, self efficacy was also recorded to have been maintained (Lorig, Ritter et al., 2001; Lorig, Sobel et al., 2001).

Health care use was another facet examined in the literature. Pre-post tests have reported reduced health service use (Lorig, Sobel et al., 1999). Longitudinal evaluation at 12 months identified that this gain was not sustained in hospital admissions as measured by length of stay (P=0.12) or physician consultations (P=0.19). However, there was a significant reduction in the number of Emergency Department presentations (P=0.01) (Lorig, Sobel et al., 2001).

2.6.4 Outcome Evaluation

Program evaluation and outcome measures are the reported final component to a comprehensive PRP. Outcome measures are usually aligned with the primary goals of the program (ATS, 1999b; BTS, 2001). The suggested minimum dataset should include the direct evaluation of dyspnoea, HRQoL, exercise tolerance, and activity levels (ATS, 1999b; Troosters et al., 2005). The costs of an outpatient based PRP have been anecdotally reported from as little as $249 (Jenkins, Cecins, & Collins, 2001) to $2615 per participant (Troosters, 2000). The cost of facilitating a CDSMP workshop for Kaiser Permanente was estimated at approximately $200 per participant (Lorig, Sobel et al., 2001; Pepper-Burke, 2003). It has been considered in the literature that

the projected 'cost saving' to an organization from provision of wellness maintenance strategies arises due to the reduced unplanned health resource use (Pepper-Burke, 2003).

2.7 Barriers to program participation

There exists few publications that have investigated barriers to enrolment or, participation in a pulmonary rehabilitation program. Yet, barriers to attendance at a cardiac rehabilitation facility have been well documented. A comparison of cardiac and pulmonary rehabilitation patients the commonalities shared by both groups include;

"Common intra-thoracic location of the pathology, the frequent co existence of cardiac and pulmonary disease, shared symptoms, such as dyspnoea, fatigue…exercise intolerance, and common rehabilitation goals" (Reardon et al., 1995 ,p.277).

These similarities allow for comparisons to be made between the two population groups. In order to develop an appreciation of factors affecting participation in pulmonary rehabilitation, knowledge of barriers to participation in a cardiac rehabilitation program may be of some benefit.

2.7.1 Barriers to participation in a rehabilitation program

The four areas that are barriers to enrolment and participation in a rehabilitation program have been commonly identified: Financial, Organisational, Social factors, and Individual characteristics. A review of each of these areas follows.

2.7.1.1 Financial factors.

In Australia, there exist no direct fiscal barrier to program attendence as public hospitals do not debit participants to attend a rehabilitation program and private hospitals directly debit the patient's health insurance company. Indirect costs may exist when the participant's hours of employment conflict with the hours the program is conducted. To circumvent vocational commitments as a barrier, one cardiac rehabilitation program had reported that their exercise class was conducted at 06:30 AM to enable people to attend class on their way to work. The authors reported that the rate of attrition was equivalent to that of other programs (Harlan, Sandler, Lee, Lam, & Mark, 1995).

Indirect financial costs associated with program participation are often subtle barriers. Exemplars include: transport costs to attend rehabilitation classes, the availability of accessible car parking to the location of the program, suitable clothes to exercise in, exercise shoes and time off work (Hellman & Williams, 1994; Young et al., 1999). Role resumption is generally considered a very good outcome following a cardiac event. However, there have been reports identifying that patients who had a higher role resumption at two weeks following hospital discharge, were less likely to participate in a rehabilitation program (Linden, 2000).

2.7.1.2 Organizational factors.

Despite the unequivocal benefits not all patients are even offered the option of rehabilitation. The type of hospital, years of experience of the physician, deteriorating clinical state of the patient are factors that may influence whether a patient is referred to a cardiac rehabilitation program. The strongest predictors of referral to a CR program appear to be age and revascularization, both being good prognostic indicators. A patient whose diagnosis is clear early in their admission is more likely to be targeted as a person who will benefit from rehabilitation (Pashkow, 1995).

Physician referral is an organizational factor that influences program participation. Ideally, referrals to a rehabilitation program should occur at an early stage in the disease process based on the 'patient's symptoms, disability and handicap' rather than referral based on the severity of lung function (ATS, 1999b ,p.1669). Lack of physician recommendation or referral to a rehabilitation program was reported as the most common reason by patients who did not attend cardiac rehabilitation. (Evenson & Fleury, 2000). Patients rarely ask to be sent to an exercise program. The ground work for patient attendance needs to begin in hospital whilst the patient is admitted with their acute event (Lane, Carroll, Ring, Beevers, & Lip, 2001).

The BTS has highlighted the importance of organizational factors such as location and provision of transport as barriers to PRP attendance (BTS, 2001) Accessibility to a PRP appears to be a barrier in many health care systems. In Australia it is estimated that fewer than one percent of Australians with moderate to severe COPD can access an annual program (Frith, 2002). Heart disease is a more prevalent chronic condition than COPD. It has previously been reported that participation in a cardiac rehabilitation program in Victoria, Australia averaged 24% of all those willing and able to attend (Sundararajan, Bunker, Begg, Marshall, & McBurney, 2004). This figure is consistent with an earlier report that 32% of eligible participants took the opportunity to participate from a sample of eight Victorian cardiac rehabilitation programs (Bunker, McBurney, Cox, & Jelinek, 1999). Similar rates of uptake for cardiac rehabilitation have been reported in other Commonwealth countries. In the United Kingdom, between 14% -23% of myocardial infarction patients, between 33% -56% of cardiac surgery patients, and between six to ten percent of percutaneous coronary intervention patients are enrolled into CR programs. (Bethell, Turner, Evans, & Rose, 2001) This figure contrasts with the reported national accessibility rate of one and a half percent in Australia, and in the UK andtwo percent accessibility in Canada to pulmonary rehabilitation programs (Brooks et al., 2007; Yohannes & Connolly, 2004).

2.7.1.3 Social factors.

Patient characteristics and available social support influence patient decision making when they are deciding if they will attend (Emery, 1995; King, Humen, Smith, Phan, & Teo, 2001; Lane et al., 2001). Caring for a dependent other, social inhibition, not owning or driving a car are cited as barriers to attending cardiac rehabilitation. People who were less likely to believe that their condition was controllable and that their lifestyle contributed to their illness were the least likely to attend cardiac rehabilitation (Lane et al., 2001). Locus of control is a phenomenon often employed to explain such beliefs. Actions that influence outcomes forms a central tenet to the concept of locus of control (Bandura, 1982). Personality has not been associated with adherence although depression, is associated with non-adherence (Emery, 1995). Voluntary choices such as diet and smoking were not found to be influences in enrolling to attend cardiac rehabilitation (Harlan et al., 1995). However, people identified with a lower baseline functional status with co-morbidities, were sedentary pre admission and had access to less income or education, were the least likely to participate in a cardiac rehabilitation program (Harlan et al., 1995).

2.7.1.4 Individual patient characteristics

In the USA, less than 25% of those identified as patients whose health would be improved or maintained by participation in a cardiac rehabilitation actually attend. Twelve months after participation in a CR program, 90% of the 25% of attendees did not adhere to their exercise program (Carlson, Johnson, Franklin, & VanderLaan, 2000). Few studies have identified who decides to enrol in a cardiac rehabilitation program (Hiatt, Hoenshell-Nelson, & Zimmerman, 1990). However those patients who did participate in cardiac rehabilitation perceived more benefits and fewer barriers and hence, were agreeable to attending (Hiatt et al., 1990).

Gender has been a reported barrier to participation in a rehabilitation program. At the time of referral, women were not as strongly encouraged to participate in a program, as compared to men (Harlan et al., 1995; Hellman & Williams, 1994). The published research cites the participation of men in cardiac rehabilitation with women, cited only to assess the effect of spouse support (Emery, 1995). This may be due to heart disease being more prevalent in men than women or, selection bias in study design. Lack of patient motivation and commitment is often cited as a barrier to enrol in an exercise rehabilitation class (Evenson & Fleury, 2000). A person's perception about their health and abilities will influence whether they decide to enter an exercise program or not. People whose baseline functional status, was active to begin with, are more likely to attend (Harlan et al., 1995). This outcome is consistent with the concept of perceived self-efficacy.

2.7.2 Barriers to CDSMP participation

Initial recruitment strategies to the Stanford model CDSMP included a letter mail out to citizens on the databases made available to Kaiser Permanente. Uptake from the mail-out was noted as a mere 5-10% (Lorig, Sobel et al., 2001). The reports in the literature have identified that of their entire population screened to participate in a formal CDSMP trial, only 47 per cent chose to participate (Lorig, Sobel et al., 1999). Further analysis of barriers to program participation have noted that men in general, and people from a culturally and linguistically diverse background were reported in the literature as less likely to participate in a program (Barlow et al., 2000; Lorig, Sobel et al., 1999). In the original Arthritic self-management studies conducted by Stanford University, the predominance of female participants (84%) was highlighted (Holman et al., 1989). Despite statistically significant results reported from program participation, the Stanford researchers had speculated in the literature whether these results would be reproducible in cohorts from different socio- economic and geographical circumstances (Holman et al., 1989). Areas in the USA with the lowest literacy and socio-economic conditions, and lack of transport reported the lowest uptake to program

participation (Pepper-Burke, 2003). This project has reported that the newspaper advertisements inviting all interested citizens to attend a CDSMP was limited in uptake with, the middle class suburbs of their catchment area, the sole source of uptake which the candidate has reported (Murphy et al., 2003). Long term attrition to follow up in the USA has identified that younger, unmarried, non -white participants were all significantly more likely to be lost to follow up ($P<0.05$) (Lorig, Sobel et al., 2001).

2.8 Chapter Summary

The rate of progression of COPD can be variable but, it is more likely with continued exposure to precipitants of the condition. Smoking status and continued adverse exposure to environmental pollutants need be identified in all program participants at each assessment point of contact to enable a fair review of the efficacy of health interventions. Although COPD is primarily a respiratory condition it has profound systemic consequences. These include exercise intolerance, muscle wasting, cardio-vascular remodelling and, a hyper-catabolic state.

Expiratory airflow limitation is the primary index of COPD pathology (Polkey, 2002). The lack of consensus between the various guidelines in grading COPD impairment must influence the reported incidence of disease severity and/or, the effects of interventions (Jenkins, 2003). The GOLD classification system of COPD severity has demonstrated the greatest correlation ($r = 0.29$) between disease severity and health care use (Tsoumakidou et al., 2004).

The largest costs of care reported in people with COPD are unplanned health care usage due to an exacerbation of the condition. An exacerbation of COPD and reduced functional status has both been reported in the literature as objective measures that correlate with disease progression. An exacerbation of COPD and maintenance of functional activity have demonstrated prognostic significance on morbidity and mortality. Prompt symptom

management has been reported to offset and delay disease progression (Wilkinson et al., 2004). In addition, mood status has been reported in the literature as an affective symptom (Anderson & Burckhardt, 1999). Optimising symptom management remains a primary ambition behind most applied health care interventions in COPD. In the 2003 Australian and New Zealand COPD-X guidelines, the expert panel proposed that patients be taught symptom recognition and timely management to contain and/or offset disease progression. The use of an action plan and self-management strategies were highlighted as possible methods to up skill the patient and their carers (McKenzie et al., 2003). There remain mixed reports in the COPD literature of the correlation between functional status and objective and subjective measures of health. This would suggest that therapies aimed at improving symptom control and functional status can result in a change in wellbeing and health care usage without any measurable change in lung function.

HRQoL may be evaluated via generic and disease specific outcome measures. Incorporating both types of measures increases the likelihood of capturing change in wellbeing and program efficacy. Generic HRQoL measures may also be used as part of a cost utility analysis. An economic analysis enables the evaluation of health care programs by their costs and consequences (Drummond, 1997). Reported indications to undertake an economic analysis include interventions that are not considered to have an effect on mortality but, may confer an effect on physical, social or psychological well being (McKie et al., 1998). To arrive at valid conclusions in the evaluation of health interventions, an economic evaluation should not be appraised independently of the clinical project (Dixon et al., 1999). There remains an absence of any published reports ranking the outcomes of health interventions in COPD by costs and consequences.

The components of a comprehensive PRP include exercise, education, behavioural change and program evaluation. However, gaps exist in the literature of the reported efficacy of these individual components to a PRP. Knowledge as to the efficacy of the non-exercise components would inform

on the utility of these components for people who cannot exercise due to concomitant ailments (ATS, 1999c).

Self management has been defined as any formal program that teaches the skills required to confidently live with a chronic condition, change health behaviours and live a functional life (Bourbeau et al., 2003; Chodosh et al., 2005). A Cochrane review examined the efficacy of self management programs applied to a COPD sample and reported none had evaluated the effect of their self-management models on exercise capacity (Monninkhof et al., 2003). A self-management program is not seen as a replacement therapy for pulmonary rehabilitation. However, the significant lack of available pulmonary rehabilitation programs means other more accessible therapies need to be evaluated for their benefit for people with COPD. There are financial, organizational, social factors, and individual characteristics that impede uptake to adjuvant therapies. These barriers need to be considered during the implementation process and with program evaluation.

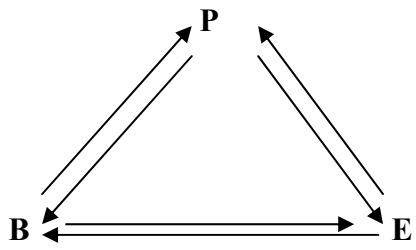
Programs without the underpinning of a developed conceptual model risk becoming operationally ambiguous, and the outcomes can be difficult to interpret. The appraisal of a tacit program risks becoming a 'black box' evaluation as the nature of the program may not be able to explain the outcomes observed, in contrast to programs with an articulated conceptual model drawn from the social sciences (Rossi et al., 2004). The literature has reported that optimisation and maintenance of the effects of a rehabilitation program requires an understanding of social learning theory and theories of behavioural change need to be imbedded in the program's practice (Berarducci & Lengacher, 1998).

Chapter Three Conceptual Models

Chapter Three reviews three of the most common conceptual models used in healthcare today. Following a review of the application, merits and limitations of these models this chapter concludes with the health model selected for this project.

Health interventions are implemented with the ambition of relieving the burden of disease and to encourage the uptake and maintenance of healthy behaviours. Human behaviours are generally regarded as quite complex. To effect a positive change in health behaviours a conceptual health model may serve as a reliable template when designing a program. There is no one particular model that can best predict or explain the uptake or, maintenance of healthy behaviours. The utility of a conceptual model rests with enabling the clinician to incorporate the determinants of behavioural change into their interventions and, by manipulating them facilitate desirable behavioural change (Price & Archbold, 1995).

Social cognitive theory (SCT) has been the dominant psychological model that has underpinned a number of health care interventions (Bandura, 1997b). SCT is based on the triadic reciprocal relationships between personal factors, behaviour and the environment (Bandura, 1982; Conn, 1998): (Figure 3.1).



Key: P Personal factors; B Behaviour and, E the External Environment

Figure 3.1: The three reciprocal relationships in social cognitive theory. (Adapted from Bandura 1982 ,p.6).

The following section will outline the basic components of social cognitive models that have sought to explain successful behavioural change.

3.1 Trans-Theoretical Model

Prochaska and DiClemente (1982) reported the development of the Trans Theoretical Model (TTM) or "stages of change" model. The process of change requires both cognitive and behavioural modification i.e. conscious decision-making and, behavioural processes: counter-conditioning, reinforcement and, stimulus control (Plotnikoff, Hotz, Birkett, & Courneya, 2001). The TTM was originally utilised for a study in smoking cessation (Prochaska & DiClemente, 1983). The TTM has had reported use as a model to explain motivational readiness for the uptake and maintenance of physical activity (Marcus, Selby, Niaura, & Rossi, 1992; Plotnikoff et al., 2001). The TTM identifies readiness to undertake behavioural change as requiring four key elements: "stage of change, self efficacy, decisional balance (pros and cons), processes of change (experiential and behavioural)" (Plotnikoff et al., 2001 ,p.442). People at different stages of change utilize these four elements to varying degrees. The uptake of a new behaviour sees the individual move through the five stages of change. These stages have been described as:

1) Pre-contemplation (no intention to change behaviour within the next six months),

2) Contemplation (no intention to change behaviour within six months),

3) Preparation (small or inconsistent changes),

4) Action (active involvement in behaviour for less than six months),

5) Maintenance (sustained behaviour change for at least six months).

(Plotnikoff et al., 2001 , p.442)

This transition is not necessarily in a linear direction as individuals cycle through the different stages and relapse before achieving Maintenance of healthy behaviour. The strength of the TTM, is seen in its utility in being able to identify at which stage the individual is situated. This information would

then allow for the prescription of health care strategies that support the participant at that point in time.

The TTM was used as a framework that examined the uptake of physical activity over a 12 month period in a random sample (N=683) of people (Plotnikoff et al., 2001). This study reported that self-efficacy increased as the individual progressed forward through the Stages. Self-efficacy has been reported as strongly correlated with exercise and other health behaviours in both pulmonary rehabilitation and participation in the Stanford model CDSMP as outlined in Chapter Two. However, Plotnikoff et al (2001) reported that the TTM was less robust in predicting movement from the pre-contemplation and preparation stages. This would appear to be a critical limitation, as many individuals would find themselves in these stages and it suggests a significant drawback in utilizing this model as a basis to map apt interventions. It had been suggested that the utility of the TTM lies as a descriptive model of the behaviour to be explained rather than as an explanatory model for health promotion or disease prevention (Bandura, 1997). In a critique of the limitations of the TTM, stages of change in behaviour, as categorized by intervals of time, was thought to be inconsistent with a genuine stage theory of personal transformation (Bandura, 1997a). A stage theory, as reported by Bandura, has three defining properties "qualitative transformations across stages, invariant sequence of change and, non reversibility" (Bandura, 1997a ,p.8).

3.2 Theory of Planned Behaviour and Reasoned Action

The Theory of Reasoned Action (TRA) (Ajzen & Fishbein, 1980) and the Theory of Planned Behaviour (TPB) (Ajzen, 1988) are two social cognitive models that have been utilised in research on physical activity behaviour. The TPB is an extension of the TRA with perceived behavioural control as an additional component included in the schema as shown in Figure 3.2.

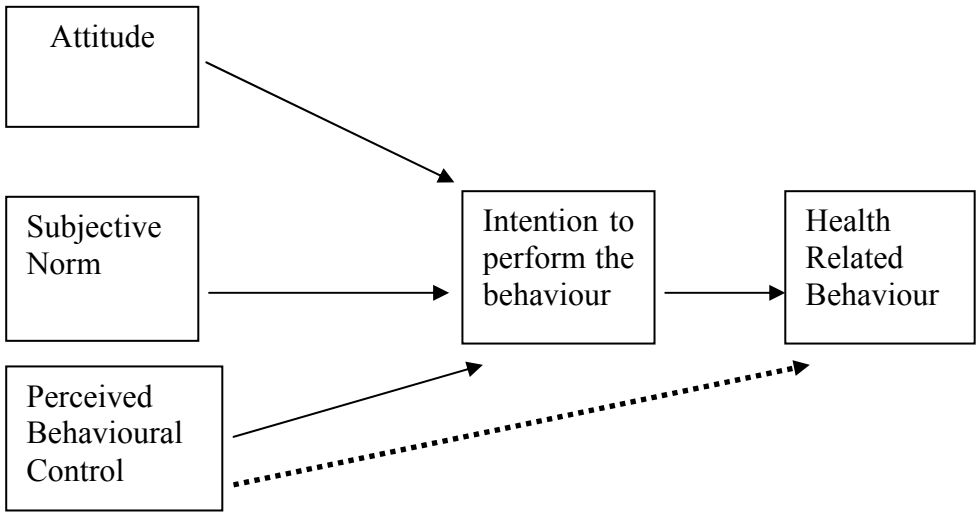


Figure 3.2: Theory of Planned Behaviour: (adopted from Ajzen, 1988).

The TRA assumed behaviour to be under voluntary control (Ajzen, 1988). Both the TRA and TPB incorporate attitude toward the behaviour and subjective norm as influences on intention to perform the behaviour. Attitude (a positive or negative position towards performing a behaviour) and subjective norm (perceived peer pressure) are major determinants of the uptake of that behaviour. The attitudinal component is developed from the person's salient beliefs and perceived outcomes from undertaking the behaviour (Godin, 1994). The subjective norm develops from peer influence on whether to perform or not perform the behaviour; this is independent of the individual's attitude to the behaviour. The attitudinal component has been reported to be a greater predictor of behaviour than the subjective norm (Blue, 1995; Young & King, 1995). Both attitude and subjective norm arise out of the individual's salient belief based structure, which in an important determinant of behavioural uptake. The inclusion of the individual's beliefs has been cited as an additional 'control' factor (Burke, 2001; Godin, 1994;

King et al., 1992). In a range of situations, individuals may perceive that they have total control or, even little control. This variability was seen as a limitation in the TRA and therefore the TPB, which included perceived behavioural control, became a necessary extension to the original theory (Burke, 2001).

The TPB has been reported as a useful framework to investigate exercise motivation during and following participation in a Phase two cardiac rehabilitation program (Blanchard, Courneya, Rodgers, Daub, & Knapik, 2002). Perceived behavioural control is a useful predictor of behavioural uptake as it incorporates real or perceived factors that facilitate or are barriers to the uptake of exercise (Blue, 1995). The TPB proposes that individuals will pursue a behaviour if they have a positive attitude to the behaviour, enjoy favourable peer support and perceive that the situation is within their control.

3.3 Self Efficacy Theory

Self-efficacy theory (SET) as posited by Bandura, is a social cognitive model that has had prior use as a vehicle to explain and predict exercise behaviour and HRQoL outcomes. This theory has been reported as the closest conceptual fit to underpinning the philosophy of the Stanford model CDSMP.

Self efficacy has been defined as "the belief of a person in his or her ability to organize and execute certain behaviours that are necessary in order to produce given attainments" (Bosscher & Smit, 1998 ,p.339). Terms related to self efficacy include: self control, self actualization, self confidence, self care agency and perceived competence (Berarducci & Lengacher, 1998). Bandura had suggested that the term self efficacy should not be confused or substituted with concepts such as self esteem or, self image as these are separate constructs concerned with judgements of self worth. In contrast to self efficacy, the latter constructs do not reflect self beliefs (Bandura, 1982, 1997b).

Self-efficacy is a dynamic, fluid state. People may have high self-efficacy in one endeavour and low self-efficacy in another. Behaviours associated with high self-efficacy are persistence and, high perseverance in the face of adverse circumstances (Bandura, 1982). Whilst behaviours associated with low self-efficacy are apathy, stress, depression and, self doubt (Bandura, 1982). Identifying low self efficacy behaviours in participants in applied health care programs allows for the implementation of 'efficacy builders' in order to modify behaviour and improve health outcomes. It had been suggested that health interventions need to be implemented in a manner that "instils and strengthens the patient's expectations not only in the efficacy of the adjuvant therapy but in their own ability to improve their health status "(O'Leary, 1985, p.448).

In SET, the reciprocal relationships between the person, behaviour and the environment do not necessarily exert equivalent or simultaneous influences. The influence that these three variables exert will depend on the individual, the activity and the situation (Stajkovic & Luthans, 1998). In the scientific literature, the environment is one determinant that in the past rarely rated a mention when reporting on the uptake and maintenance of behaviour change arising from health interventions. In an attempt to maintain an exercise program the environment the exercise is conducted in, for example a structured group 'maintenance' program as compared to solitary exercise, may influence adherence, over the duration. Social support, positive feedback, encouragement, participation with others, all create an environment, which may facilitate participation and adherence over the duration. Interestingly, SET is the only social cognitive theory that includes the environment as a significant determinant that influences outcomes. A person's behaviour is considered to be influenced by cognitive factors in addition to the environment in which the behaviour is performed (Clark & Dodge, 1999; Conn, 1998; Shortridge-Baggett, 2001).

3.3.1 Sources of Efficacy

SET is concerned with examining the assessments one makes rather than the current skill base one has (Bandura, 1997b; McAuley & Courneya, 1992).

Self-efficacy is a concept that embodies what a person thinks they can do. This judgment Bandura has termed Efficacy Expectation. In contrast, the judgment that undertaking a behaviour will result in a positive outcome has been deemed an Outcome Expectation (Kaplan, Atkins, & Reinsch, 1984). The model espoused by Bandura is illustrated in Figure 3.3.

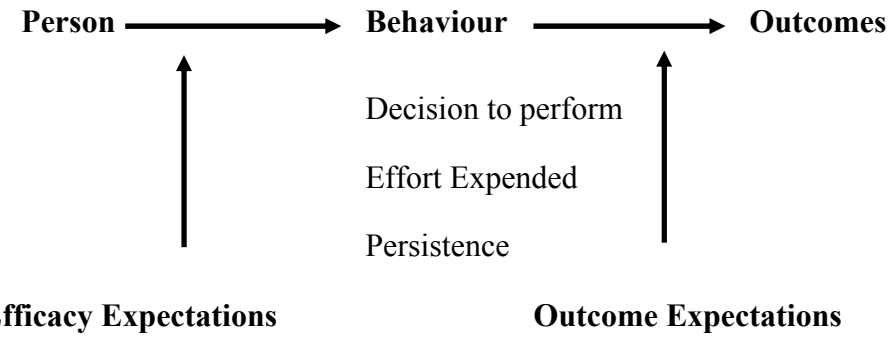


Figure 3.3: A linear model of Bandura's theory: (Jeng & Braun 1994 ,p.429).

Efficacy expectations are reported as powerful mediators of behavioural performance which leads to their being a major determinant on outcomes (Clark, 1996; Conn, 1998; Hofstetter, Hovell, & Sallis, 1990; Jeng & Braun, 1994). Efficacy expectations can be drawn upon by the individual to determine whether to engage in a behaviour and the degree of effort and persistence to expend in order to achieve the outcome (Bandura, 1982; Jeng & Braun, 1994; Lev, 1997; Stidwell & Rimmer, 1995). Efficacy expectations have been reported to vary along three dimensions: magnitude, strength and generality (Bandura, 1997b; Clark, 1996; O'Leary, 1985; Shortridge-Baggett, 2001; Stidwell & Rimmer, 1995). These three dimensions have been summarised:

i) Magnitude is the perceived difficulty or effort she or he will encounter in the task. For example, a person may be able to undertake an endeavour at their own pace but not under stress. Therefore, the magnitude of the task varies according to the conditions. Efficacy expectations may therefore vary with the conditions.

ii) Strength refers to the person's persistence or perseverance with a specific behaviour despite frustration, pain, failure or adverse circumstances. The exercise of control over a challenging situation is a significant efficacy builder and "a critical aspect of self management" (Bandura, 1990, p.287).

iii) Generality concerns whether changes in self efficacy transfer to other behaviours or situations i.e. "the degree to which one overcomes a fear in one activity will transfer to other, non related fears" (Stidwell & Rimmer, 1995 ,p.58). One reported example of this generality was a cardiac patient's improved exercise treadmill tolerance translated to increased unsupervised exercise in their own home (Strecher, DeVellis, Becker, & Rosenstock, 1986).

Outcome Expectations (as illustrated in Figure 3.3) refer to the person's beliefs that a given behaviour will yield desired results and increases the likelihood that the behaviour will be attempted again (Clark & Dodge, 1999; Conn, 1998; Jeng & Braun, 1994; Kaplan et al., 1984; Shortridge-Baggett, 2001; Siela, 2003). Beliefs about personal efficacy develop from the cognitive appraisal of four levels of information (Hofstetter et al., 1990; Shortridge-Baggett, 2001). These four sources of information are:

i) Performance accomplishment (mastery); the most influential source of personal efficacy (Conn, 1998). Successful performance in a task (mastery) is the greatest incentive for behavioural change (Bandura, 1997b). Participation in an exercise program or completion of a self-management program would be an example of a personal accomplishment and mastery of circumstance. The outcome of an exercise test could also be a mastery experience for the participant (Lox & Freehill, 1999).

ii) Vicarious experience is considered, after performance accomplishment, to be a strong determinant of behavioural change (Clark & Dodge, 1999). Vicarious experiences arise from observations of social role models such as family, peers, clinicians

and the media (Clark, 1996). Role models of healthy behaviours from within one's peer group enable a patient to observe how to imitate or reinstate control of their situation (Bandura, 1990). In this project, participants have the opportunity to mimic or model the uptake of healthy behaviours as mastered by members of their peer group.

iii) Verbal persuasion; includes the positive and reinforcing feedback participants in a program receive from program facilitators and their peers. Praise and encouragement for example have been reported to influence self efficacy to exercise (Fletcher & Banasik, 2001). The credibility, expertise, and prestige of the source of the praise and encouragement will determine the degree of influence this efficacy builder has on the participant (Stajkovic & Luthans, 1998; van der Bijl & Shortridge-Baggett, 2001).

iv) Physiological/emotional arousal, has been considered to be the least influencing source of efficacy and refers to the emotions experienced by the individual such as depression, anxiety, happiness or sadness (Lox & Freehill, 1999).

Self - efficacy is a cognitive mediator to action (Bandura, 1982). A change in one or more of these four dimensions of efficacy should, according to SET, influence the uptake or alteration in behaviour.

3.3.2 Outcomes of Efficacy

Both the Efficacy and Outcome Expectations link cognitive beliefs to behavioural outcomes (Strecher et al., 1986). These outcomes are goal linked. However, the difficulties encountered in the attempt to modify 'unhealthy' behaviours receives little consideration in the risk factor modification literature (Jeng & Braun, 1994). Bandura suggested that the general public, in a number of studies, are motivated by health losses rather than health benefits when it comes to modifying their lifestyle (Bandura, 1997b). People may

cease an 'unhealthy' behaviour such as cigarette smoking for reasons not connected to their health for example rather, to seek social approval. In this scenario, smoking cessation offers the immediate reward of social approval. Possibly the challenge rests with the ongoing maintenance of smoking cessation. The likelihood of a person to cease or undertake an activity will appear to depend on their perception of their ability to achieve the expected outcome. Perceived self-efficacy is central to this behavioural change.

Successful behavioural change requires a link between cognitive expectations and goals. Skills in self -management need to be learnt. People need to:

i) learn how to monitor the behaviour they wish to alter,

ii) set short term goals and action plans that act as an incentive to attain the success needed for long range efforts and,

iii) enlist social support and rewards in order to succeed (Bandura, 1997b).

The Stanford Model's CDSMP is aligned with these concepts. In this six-week program, participants are encouraged to set weekly goals and receive weekly feedback on their performance. Self regulation is not achieved merely by personal discipline (Bandura, 1997b). Cognitive and environmental factors influence outcomes and the manipulation of these variables should optimize the uptake of health behaviours.

There are a number of health conditions that have reported the use of self-efficacy theory as their framework to explain likely outcomes. Bandura's theory suggests that changes in self efficacy should be reflected in changes in performance (Kaplan et al., 1984). In patients with heart disease, the maintenance of exercise behaviour has been reported to correlate with self-efficacy to exercise (Carlson et al., 2001; Cheng & Boey, 2002; Clark & Dodge, 1999; Jeng & Braun, 1994; McAuley & Courneya, 1992; McAuley, Shaffer, & Rudolph, 1995; Siela, 2003; Vidmar & Rubinson, 1994). In addition, a study based on an arthritic population had identified an association between increased self-efficacy and a reduced unplanned need for hospitalization (Miller & Cronan, 1998). The utility of SET appears to rest

with its ability to recognize the likelihood of adherence to healthy behaviours (task efficacy) and, as a concept that can identify barriers to the uptake of healthy behaviours (barrier efficacy) (Tsay & Chao, 2002).

A review of studies that has examined self efficacy in people with COPD was published (Kohler, Fish, & Greene, 2002). Self efficacy was reported to directly correlate with HRQoL (r = 0.49) (Kaplan et al., 1984), (r = 0.93) (Tu, McDonell, Spertus, Steele, & Fihn, 1997), moderately with the report of respiratory symptoms (r = - 0.56) (Scherer & Schmieder, 1997) and, exercise tolerance (r = 0.43)(Scherer & Schmieder, 1997). All of these studies identified improvements in the participants level of self-efficacy occurred despite no restoration in their physiological health status.

As a follow up to these findings, Kohler (2002) initiated a study of medication adherence in a COPD population (n=208) with severe COPD (mean FEV_1 41% predicted). Functional status was reported to be directly proportional to levels of self-efficacy, and independent of disease severity as measured by FEV_1. In more recent times, a correlational study of COPD patients (n=97) examined self-efficacy and dyspnoea as a predictor of functional exercise tolerance (Siela, 2003). In this convenience sample, ratings of self-efficacy predicted 36% of the variance in exercise tolerance. Physiological status had been identified in Chapter Two as insufficient to explain functional exercise tolerance in the COPD population. The findings from these reports correlate with Bandura's research findings, "functional limitations may be governed more by beliefs of capability than by degree of actual physical impairment" (Bandura, 1997 ,p.300) as cited in (Kohler, 2002).

The role of self efficacy and social support in predicting exercise behaviour was examined in a randomized controlled trial, in a cardiac rehabilitation setting (Carlson et al., 2001). These researchers randomized participants (n=80) to two cardiac rehabilitation programs. One group was a staff mediated program ("usual care") and the other was a modified program that emphasized independent exercise and included support meetings with six months follow up. Self-efficacy was found to be a predictor of exercise frequency ($P<0.01$). The group who were supervised by staff had three times

the level of attrition than the group who were encouraged to initiate independent exercise. From this study, it may be concluded that efficacy builders need to be incorporated into the intervention in order to maintain the benefits once the supervision has stopped so that the desired behaviourial change (to keep exercising) is maintained. It would seem that ratings of self efficacy, can be valid predictors of health related actions (Berarducci & Lengacher, 1998).

An outpatient pulmonary rehabilitation program (N=40) sought to measure changes in a six-minute walk test, in terms of quality of life and self efficacy (Lox & Freehill, 1999). These findings revealed an increase in self-efficacy together with an increase in exercise tolerance. The Lox & Freehill study provides further evidence that improved self-efficacy is both an important outcome and an enabling component that results from participating in a pulmonary rehabilitation program. Hence, strategies that build on self-efficacy need to be incorporated into programs to generate a lasting effect. Promotion of a "sense of personal efficacy not only promotes health but aids physical and social recovery" (Bandura 1982, p.206).

3.4. Summary

The use of conceptual models in applied health care interventions enables the clinician to incorporate the determinants of behavioural change into their interventions and, by manipulating expectancies and reinforcements facilitate desirable behavioural change (Price & Archbold, 1995).

A number of conceptual models share common elements. The cognitive and behavioural change required to initiate a change in behaviour have been reported as components in the TRA, TPB and TTM. These models have all identified that the individual's salient beliefs determine uptake of new behaviour. The TTM had identified the stages of change people may cycle through before reaching the maintenance of healthy behaviours. The TTM reported that individuals may cycle through stages and relapse. However, critics of the TTM have suggested a genuine stage theory should be unidirectional with non-reversibility. The underlying premise in SET is the

perception of whether an activity can be performed. This perception will determine whether the activity is attempted. In SET, the reciprocal relationships between the person, behaviour and the environment do not necessarily exert equivalent or simultaneous influences on the individual. The influence these three variables exert will depend on the individual, the activity and the situation (Stajkovic & Luthans, 1998).

Programs that are aligned with a conceptual health model should be able to minimise the risk of becoming operationally ambiguous or generating outcomes that are difficult to interpret. While there were a number of health models this project could have used, this project adopted self-efficacy theory as the conceptual basis in the design and delivery of the interventions. Self-efficacy had been reported in this literature review as a likely mediator of improved health outcomes for participants in the Stanford model CDSMP and also in rehabilitation programs. Based on the available evidence, efficacy-enhancing strategies are considered to be a necessary component to an effective healthcare intervention and should be included as an outcome measure. The aims of this project are presented in the next section.

3.5 Thesis aims

"Hypotheses are like nets; only the one who casts will catch" (Novalis, 1929 ,p.424).

COPD is a prevalent chronic condition. The national prevalence has also been reported to increase with age (AIHW, 2005a). With advances in health care, many people are living longer and thus, a chronic disease such as COPD will have a significant and ongoing influence on their health and quality of life. The ability to manage with a chronic illness often differentiates those who are incapacitated from those who continue to lead full and active lives (Lorig & Holman, 1993).

Adjuvant therapies as outlined in this thesis can generate a delay in disease progression, improve health care usage, symptom control and HRQoL without a measurable change in health status. Reduced functional status has been identified in the literature as a key feature of disease progression in COPD

(O'Shea et al., 2004). An absence of evaluating the efficacy of novel therapies on functional status has been identified as a limitation in the COPD literature (Monninkhof et al., 2003). A randomised controlled trial that evaluates whether participation in a self-management program can improve functional status in COPD has yet to be reported. This study will evaluate the efficacy of this novel therapy as compared to a conventional strategy in patients with COPD.

Strategies such as self-management programs trialed in COPD have concentrated on being disease specific didactic programs (Monninkhof et al., 2003). While a self-management program is not designed to be a substitute for a PRP, expert guidelines have acknowledged that it is important in the management of COPD to identify programs that may be of benefit to those who can't exercise due to concurrent ailments (ATS, 1999b). Due to the recognised incidence of concomitant ailments in people with COPD, participation in each disease specific education program would generally be regarded as burdensome. Could a generic program such as the Stanford CDSMP aligned with self-efficacy theory generate improved health outcomes for the COPD patient?

In addition, a PRP is recognised as a conventional therapy for people with COPD. Published randomised controlled data strongly suggest that a PRP may improve functional capacity, HRQoL, optimise symptom control and reduce unplanned need for health care use. However, the utility of a maintenance pulmonary rehabilitation program is speculative due to the mixed results reported in the literature (Vale et al., 1993).

Increasingly, the evaluation of programs aimed at people with COPD need to consider the moderating effects of gender when reporting program efficacy. Most of the HRQoL data in COPD has been studied only in men (Foy et al., 2001) due to a historically greater prevalence (Domingo-Salvany et al., 2002), in contrast to today's figures (AIHW, 2005a). This would suggest gender should be considered when evaluating the efficacy of conventional adjuvant therapies applied in this patient group.

This study has three aims. To examine whether a self-management program can improve health outcomes for people with COPD when participants are re-evaluated post program. The first aim is a preliminary step to the second aim, which is to evaluate the effects of the interventions over 52 weeks of follow-up. The third aim is identify the costs of care for people with COPD and whether any one group reported improved health outcomes.

Based on the literature review presented in Chapters One through to Three, the Stanford model CDSMP, PRP and PRP+m were the three interventions selected as the independent variables for this project. The duration and effect of participating in these interventions will be compared with the responses of participants from the control group. The literature reviewed in this thesis has identified that COPD profoundly impacts on the individuals' functional status, symptom control, HRQoL and increased need for health resources. These areas of impact were selected as the dependent variables for this project.
This project will examine the effect of the three adjuvant therapies described above by means of the following null hypotheses:

1) There will be no difference between the Control and the six-week CDSMP or PRP groups at week seven in functional status, symptom control, HRQoL and self-efficacy.

2) There will be no differences between the Control, the CDSMP, PRP or PRP+m groups or by gender in functional status, symptom control, HRQoL, self-efficacy and unplanned health resource use over the 12 month follow up period in this study.

3) An economic evaluation will demonstrate no difference between groups over time.

A better understanding of the efficacy of novel and existing adjuvant therapies for people with COPD should provide greater evidence for their cost effective application and support their availability for people disabled by this chronic condition.

Chapter 4 Method

4.1 Study setting and funding

The Victorian state government Department of Human Services allocated all public funded acute care hospitals in 2002 a grant in aid commonly referred to as HARP Funding. HARP is an acronym for Hospital Admission Risk Program. The interventions in this project were funded from Hospital A's HARP funding.

4.2 Study design

4.2.1 Randomised controlled trial

The project was a randomized controlled study with parallel group repeated measures and longitudinal follow up focusing on improving health outcomes in people with COPD. A randomized controlled trial is an experimental design characterized by the manipulation of the independent variable; random assignment of the subject to a group or groups and, all other factors being controlled (Ogier, 1998).

The merit of an experimental design is that "extraneous variables, that might constitute threats to internal validity" are controlled for (Beanland et al., 2000 ,p.201). Extraneous variables may be antecedent or intervening. Examples of antecedent variables include age, gender, socio-economic status and pre morbid health status. Intervening variables may occur during the course of the study and are unrelated to the investigation but may influence the dependent variables. For example, a media report on exercise may influence a subject's attitude to exercise (Beanland et al., 2000). The randomisation of subjects allows for the spread of extraneous variables between each group. This procedure should allow differences in the outcomes of the dependent variables to be attributed to the experimental treatment (Beanland et al., 2000; Beller, Gebski, & Keech, 2002; Hopkins, 2000). When randomization is conducted

properly, this study design is considered to be optimal (the 'gold standard'), for applied clinical health investigations. The inclusion of a control group in a study design should eliminate the effect of extraneous variables in the outcome analysis.

The control group in this study formed part of an existing study that was conducted at Hospital B, as outlined in Chapter One. The data from the other arm (i.e. PRP) of the Hospital B study will not be included in the analyses presented here. For the purpose of this project, Hospital B's control group are used as a historical comparison group that allow a comparison to be made between usual care for people with COPD and, participation in one of this project's intervention groups. The control group received usual medical care and completed the outcome measures at the same time points as the intervention groups at Hospital A. A flow chart was constructed to describe the project design and follow up assessments: see Figure 4.1.

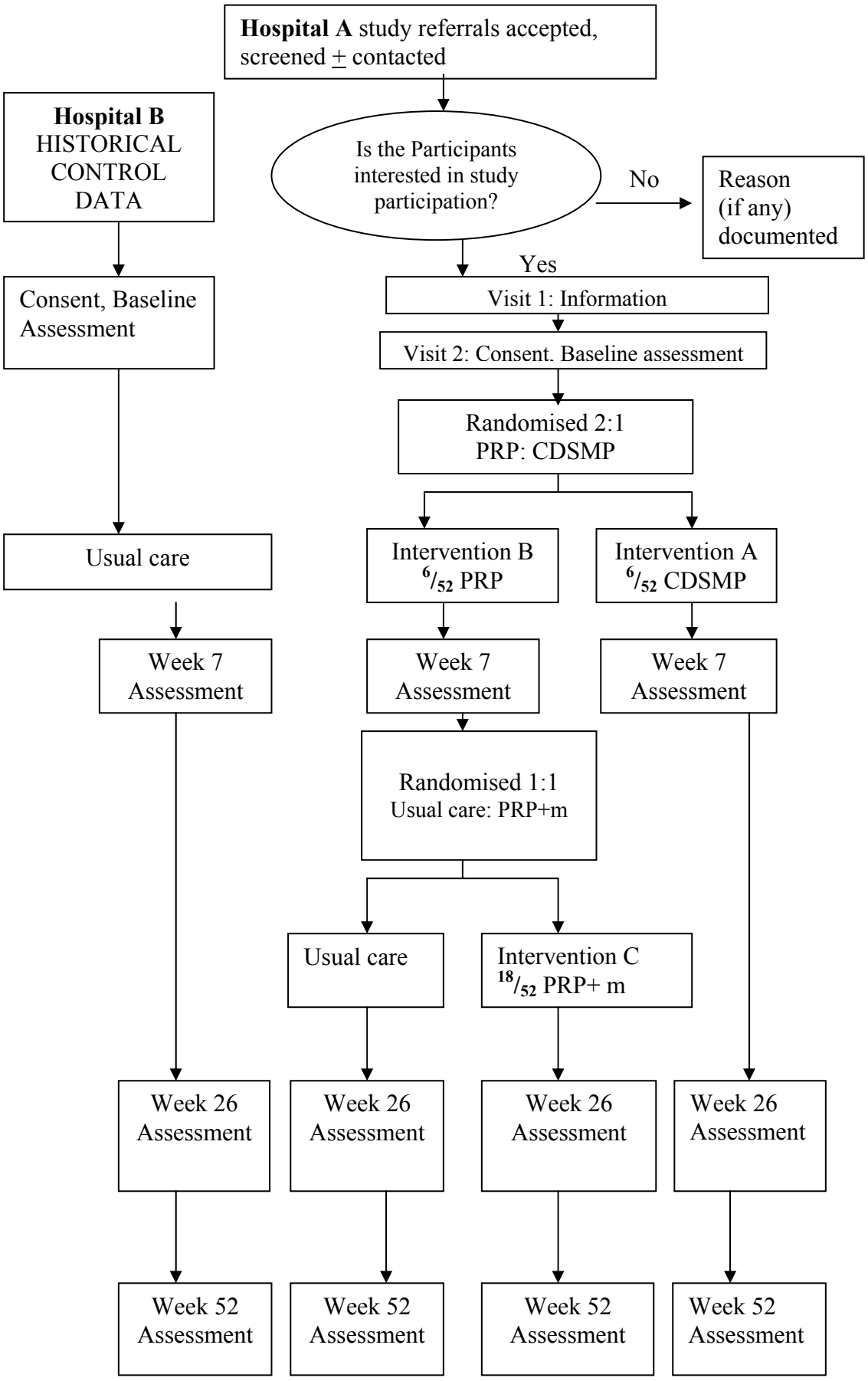


Figure 4. 1: Flow chart of study recruitment, randomizations and interventions

4.3 Participants from Hospital A

4.3.1 Recruitment

This project was reviewed and approved by both the Human Research and Ethics Committee of Hospital A and the University. The respiratory physicians at Hospital A were informed of the study and referral proformas and a brochure outlining the study was produced. Referrals were encouraged from all health care clinicians affiliated with Hospital A. I informed Hospital A's Medical, Nursing, and Allied Health departments of the COPD study in person, via group in-service, individual meetings and, the delivery of referral forms and pamphlets to their offices. In addition, referrals were encouraged from all health care clinicians whose patients resided in Hospital A's catchment area. This study was also promoted through the website of the Australian Lung Foundation. The weekly electronic mail of the Metropolitan's Northern and Western Division of General Practitioners were forums utilized regularly to promote the study to local medical general practice clinics.

The participant's signature on the consent form signified consent to participate in the study: (Appendix 2). A participant could leave the study at any time and consent would cease at that moment. Recruitment commenced on February 26, 2002 and ceased on December 23, 2003.

4.3.2 Determination of sample size

Studies that assess equivalence are undertaken to compare a new treatment/ medication as compared with an existing treatment (Jones, Jarvis, Lewis, & Ebbutt, 1996). The power calculation to determine 'equivalence' has been established (Jones et al., 1996): $n= 2 \cdot \partial^2 / \Delta \cdot (z(1-\alpha) + z(1-\beta/_2))^2$

a two sided 95% CI interval using the tables of normal distribution identified:

$z(1-\alpha) = z_{(0.975)} = 1.96,\ z(1-\beta/_2) = z_{(0.90)} = 1.28;$

$n= 2 \cdot \partial^2 / \Delta. (1.96 + 1.28)^2$ (Jones et al 1996 ,p.37).

the number of study participants required: $n = 2.60^2 / 40^2 . (1.96 + 1.28)^2$

where: ∂: the variance in baseline walking distance measured in the ISWT

Δ: the interval range i.e. $\pm$ 40 metres in distance walked (Dyer 2002).

n=47 per group which would be a total of 141 study participants.

4.3.3 Power analysis

In addition the required sample size for specific study measures were determined by established methods (Norman & Streiner, 1999). The improvement in functional capacity, HRQoL and reduction in unplanned hospital readmissions (time to an exacerbation of COPD) were considered primary endpoints.

Functional capacity: The ISWT (Dyer et al., 2002): $n = 16 \times \left(\frac{s^2}{d^2} \right)$

n= $16 \times \left(\frac{108^2}{65.6^2} \right)$ =2.7; n= 3 participants.

where: α =0.05, significance = 0.8, s = standard deviation, d = mean differences

HRQoL: the St George Respiratory Questionnaire (Schunemann, Guyatt, Griffith, Stubbing, & Goldstein, 2002):

$n = 16 \times \left(\frac{18.8^2}{9.5^2} \right)$; n=63 participants.

An audit of all unplanned COPD admissions in the preceding four years at Hospital A prior to the start of this study was undertaken. There was a mean readmission rate of 21% in this patient group from index admission as reported in Chapter One. Through proportional analysis using Minitab 4.0 (Minitab Inc. PA. USA), to detect a difference of a 15% reduction in unplanned readmissions for COPD i.e. a readmission rate of 7% (where α =0.05, significance = 0.8); n= 96 participants.

In summary, the average of these calculations identified a need to recruit 120 patients overall. Allowing for an attrition rate of 20%, there would be approximately 100 patients available for analysis. This figure was seen as both achievable and sufficient to compare interventions and identify the trends in unplanned readmissions for COPD, exercise capacity and HRQOL.

4.3.4 Participant selection

Participants were eligible to be enrolled in the study if they met all of the following criteria:

- undertake (or have had) a Respiratory Function Test (RFT) within the 12 months prior to trial entry to confirm the diagnosis of COPD.
- intact cognitive function (to enable self completion of questionnaires).
- reside or work in the catchment area of Hospital A; to enable a sample set of people with a similar socio-demographic profile.
- had experienced a moderate level of self reported dyspnoea as described by the MRC Dyspnoea scale.
- clinically stable and/or discharged from hospital for a minimum of four weeks before trial entry, (to ensure that participants were sufficiently well to engage in the intervention).
- literate in English (in order to be able to participate in the CDSMP and/or enable completion of self administered questionnaires at assessment time).

In addition, participants required medical clearance before commencement in the study. This was to ensure that the participants was experiencing optimal medical management before study entry.

Study exclusion criteria included:

- completion of a pulmonary rehabilitation program in the previous six months, (to ensure the absence of any potential 'carry over' effect from earlier interventions).

- any medical condition that could place a patient at greater risk during the assessment procedure or gymnasium program. Medical conditions considered an absolute contraindication to exercise include: malignancy, aortic stenosis, known aneurysm or acute infections. Other conditions reported as relative contraindications to exercise testing include electrolyte abnormalities, end stage renal failure, unstable angina and, poorly controlled hypertension or, metabolic conditions (ACSM, 2000a; ATS / ACCP, 2003; Morgan, 2000).

Participants referred to the study were contacted via telephone three weeks following hospital discharge if they had been an inpatient or sooner, if they were an outpatient. Interested participants and their family were then invited to attend an appointment to outline the study. Prospective participants were encouraged to take the information sheet and consent form home and discuss with their family members and/or local health care provider. They were then contacted by telephone within the next three days to gauge their interest in participating in the study. The second telephone call confirmed an appointment time to present to Hospital A for a baseline assessment.

Baseline assessment was conducted in the fortnight prior to the participant's randomization to an intervention group. All study participants at Hospital A were randomized to either Intervention A (the six-week CDSMP) or, Intervention B (the six-week PRP group). Participants of Intervention B were re-randomised to Intervention C maintenance exercise (PRP+m) or usual care following the week 7 assessment.

4.3.5 Randomisation to groups and blinding procedures

All participants consented to participate in the project prior to randomisation. Study participants at Hospital A were randomly allocated into either intervention group A or B (the CDSMP or PRP) by selecting a seed envelope.

A seed envelope was 8 x 4 cm in size, opaque in colour where the contents were not visible. The contents inside the envelope became the intervention

group the participant was randomized to. The seed envelopes were created in batches of thirty by the candidate consisting of 20 PRP and 10 CDSMP slips of paper lodged inside the envelopes. Two PRP and one CDSMP envelopes were stapled together. These three envelopes were shuffled by hand and the participant selected one envelope out of a group of three. Participants had a 2 in 3 chance of attending pulmonary rehabilitation and a 1 in 3 chance of attending the CDSMP: see Figure 4.1. To ensure the integrity of the randomization process, the participant's selection of a seed envelope occurred with their family member(s) and the candidate present.

Randomization at week 7 for the PRP arm was in a similar manner. The re-randomization post PRP at week 7 could therefore not introduce bias into the initial six-week PRP prescription as the nurse and participants were blinded to who would or would not, continue in a structured exercise (maintenance) program. Randomisation at baseline and week 7 occurred following completion of these assessments. This ensured the outcomes from the randomization process could not influence the assessments.

Ideally in a randomized controlled study, both the assessor and the participant would be blinded to the participant's group allocation. As both initial interventions were quite different, it would not be possible for the participants not to be aware which group s/he had been allocated to and still provide informed consent.

An assessor blinded to the intervention the participant has been randomized to would be advantageous. Due to study constraints, the candidate facilitated the assessments and the interventions. This has to be acknowledged as a limitation to what was otherwise a stringent process. Where one nurse conducts all of the experiments with a structured protocol that can be used by others, this has been reported to reduce the variance of the treatment between subjects, increase the internal validity and give a higher probability of the reproducibility of the experiment (Carrieri-Kohlman et al., 2001). At the same time, this control of the interventions also decreases the external validity of the experiment.

4.4 Schedule, format and method for data collection

Baseline assessment was conducted in the fortnight prior to the participant's randomization to an intervention group. All participants were reassessed post intervention at week seven in the same format as their baseline assessment. Participants in this project did not have access to their previous responses when completing the same questionnaire at follow-up assessments at week 7, 26 or 52. In a randomised controlled trial with HRQoL and other measures, there was no statistically significant difference in responses on questionnaires when participants had access to their prior answers in a longitudinal follow up design following pulmonary rehabilitation attendance (Schunemann et al., 2002). Each assessment was allocated a minimum of 90 minutes for participants to undertake the two exercise tests and answer the questionnaires by self-completion. If participants were unwell their follow-up assessment was rescheduled as soon as practicable after the illness and followed the original timetable of scheduled assessments as closely as possible. Participants from intervention C (i.e. PRP+m) who did not participate in the intervention but elected to continue in the study also followed the original timetable of scheduled assessments for week 26 and 52 as closely as possible. All assessments were conducted in identical format for each assessment and each study participant.

Upon completion in the study at twelve months, the participants was then offered a place in the other intervention group so that s/he had the opportunity to participate in both intervention groups should s/he choose as stipulated in the consent form.

4.5. The Interventions

All interventions commenced at 9.30 AM to enable participants to travel on the roadways during off peak times and be home in time for their midday meal and any special medication requirements. Car parking for the study participants was paid for by Hospital A for those who were able to negotiate their own transport. The Hospital's volunteer drivers and the Veteran's Affairs Department (transport division) were contacted to register the study and arrange transport to and from the interventions and assessments as required. The interventions undertaken in this project are summarized as follows:

4.5.1 Intervention A: the Stanford Model CDSMP

The CDSMP is a two and a half hour generic program that runs for six weeks. It is run by accredited CDSMP leaders with a small sized group using a standard reference text. The CDSMP was facilitated by two Arthritis Victoria accredited course leaders. The co –leader was a male peer or clinician, to ensure optimal role modelling, for a mixed group (Bandura, 1997b). The inclusion of a peer leader is consistent with social cognitive theory, in that people learn from a comparative force (Bandura, 1997).

The Stanford model CDSMP was taught using a standardized protocol, (Lorig & Arthritis Victoria, 1999). Group size was set as a minimum of eight participants, maximum of 14, in order to optimize group dynamics. The process of implementing the Stanford model CDSMP at Hospital A has been previously reported by the candidate in the peer reviewed literature (Murphy et al., 2003). The number of COPD participants in each CDSMP group in this study was kept to approximately fifty percent of the group, which we have previously reported (Murphy et al., 2004). This procedure was in keeping with the philosophy behind the Stanford CDSMP that similar challenges and concerns are generated in all long-term health conditions and meetings should not be disease specific.

The "Living a healthy life with a chronic condition" (Lorig et al., 2000) text was a resource loaned to the participants for the duration of the intervention.

The text enabled participants to read up in depth on the topics explored in the peer support meeting. Topics covered in the six-week program are presented in Appendix 3. All CDSMP graduates were awarded a certificate of attendance. For the purposes of this analysis, successful completion of the CDSMP was defined as having attended 5 out of 6 peer support meetings.

4.5.2 Intervention B: PRP

The pulmonary rehabilitation program was conducted by a registered nurse accredited in advanced cardiac life support.

This intervention was assisted by the employment of a physiotherapist for up to three hours each week to manage the class size. Group size was set as a minimum of five and, a maximum of 12 participants to optimize group dynamics. The six-week PRP intervention was conducted twice a week for up to ninety minutes at a time. There was an expectation that participants would exercise on the days they were not in the gymnasium and record this in their exercise diary: (Appendix 4). The PRP participants had their diary reviewed at the commencement of each class. Stretching exercises that could be performed while seated were incorporated into this diary so that participants would continue their exercising at home. These callisthenic type stretching exercises: trunk rotations, shoulder and chest stretches and side stretches were adapted from an exercise manual *Exercise Programming for Older Adults* (Caldwell, 1996). The same stretching exercises were utilized at the commencement of each gymnasium class. Each study participant was encouraged to lead the group in a stretching exercise. Chair based stretching exercises were specifically sought as it was speculated that there should be a higher uptake of exercise stretches in the participants home environment if they could be performed by a sedentary population whilst seated.

Measurements of heart rate, respiratory rate and oxygen saturation were recorded at baseline, midway and upon completion of each exercise activity. Additional measurements were taken if the participant became light headed, diaphoretic, acutely dyspneic, cyanosed or complained of chest pain. In

conjunction with these measurements the participant's effort and dyspnoea through out each activity was monitored using the Borg Scale.

The Borg Score for dyspnoea, is a ten point category ratio (10-CR) vertical scale with written descriptors of increasing intensities of dyspnoea (Mador, Rodis, & Magalang, 1995). This scale was employed to guide any increase in time on activities in conjunction with measurements of oxygen saturation and vital signs: (Appendix 5). The Borg scale (Borg, 1982) is a commonly used tool to gauge effort in pulmonary rehabilitation exercise programs (ATS / ACCP, 2003; Mahler, Ward, & Mejia-Alfaro, 2003). The limitation of using heart rate as the criterion measure to increase exercise intensity can be flawed due to the effects of some medications or, central limiting factors (e.g. cardiac or respiratory disease) which may mean that a target heart rate may not be achievable in order to achieve an exercise training effect. The Borg Scale is not an outcome measure in this study, however its purpose in the gymnasium was to serve as a guide to dyspnoea and effort tolerance. Its use in this study will be described and, its utility briefly reported here.

Participants were exercised to a rating of three to four (moderate to somewhat severe) on the Borg category ratio (CR-10) scale. This degree of effort induced dyspnoea has been reported with other programs (Nici et al., 2006; Young et al., 1999). The validity and specificity of the Borg scales have been established (Ferrer-i-Carbonell & van Praag, 2002; Grant et al., 1999; Kendrick, Baxi, & Smith, 2000; Mador et al., 1995; Mahler & Mackowiak, 1995).

Borg's rate of perceived exertion (RPE) scale was an additional tool used in the training program as a marker of exercise intensity. The scale consists of numbered categories 6-20 with written descriptors: (Appendix 6). This scale correlates with maximum heart rate i.e. heart rate of 60-200 beats per minute in healthy participants (Borg, 1982; Hughes & Pride, 2000). The RPE scale in the range of 11-13 has been reported to correlate with exercise intensity of 50-85% of maximum work rate (VO_{2max}) in a cardiac rehabilitation program when measured with oxygen consumption (Joo et al., 2004) and healthy people (Whaley, Brubaker, Kaminsky, & Miller, 1997). The RPE scale has been

reported as a valid and reliable tool to gauge exercise effort in people with COPD (Horowitz et al., 1996) and heart failure (Brubaker, Marburger, Morgan, Fray, & Kitzman, 2003). However, it is a tool not without critics (Lamb, Eston, & Corns, 1999). Tools that enable participants to quantify their exercise effort and dyspnoea were included in this study as an adjunct to the measurement of haemodynamic parameters. The primary consideration was participant safety.

Upper limb weight training consisted of two sets of five repetitions increasing in mass, up to 2.5 kg, as tolerated. Upper limb exercises were confined to work on the biceps, triceps and lateral muscles. Hand weights increased each week dependent on the participant's report of dyspnoea as measured with the Borg scale. Up to five minutes of progressive stair climbing was an additional component included in the intervention. Climbing stairs for a set number of minutes as tolerated by dyspnoea is an established PRP component (McGavin, Gupta, Lloyd, & McHardy, 1977). Additionally, up to twenty minutes of stationary cycling (no resistance) was included in the PRP prescription.

It is possible for people with COPD to exercise at 60-75% of their maximum work rate (ATS & ERS, 1999). Each participant's treadmill walking program was initially commenced at 70% of their ISWT results. Table 4.1 was devised for ease of use to correlate the results of the ISWT with the target speed the treadmill exercise would commence at on day one week one of the intervention.

Table 4.1: Treadmill target reference table

Shuttle Level	Shuttles per level	∑ Total	M/sec	Km/hr	Target speed Km/hr
1	3	3	0.5	1.8	1.3
2	4	7	0.67	2.41	1.7
3	5	12	0.84	3.02	2.1
4	6	18	1.01	3.34	2.5
5	7	25	1.18	4.25	2.9
6	8	33	1.35	4.86	3.4
7	9	42	1.52	5.47	3.8
8	10	52	1.69	6.08	4.3
9	11	63	1.86	6.69	4.7
10	12	75	2.03	7.31	5.1
11	13	88	2.2	7.92	5.5
12	14	102	2.37	8.53	5.9

Treadmill speed was increased by 10% when the participant could walk for fifteen minutes continuously with, a Borg score of < 4. Once a participant could walk continuously for 20 minutes or, one kilometre, an incline of one to two degrees as tolerated was included in their walking program. Exertional de-saturation below 85% was offset by the administration of continuous oxygen therapy titrated to maintain arterial SaO_2 to 90%. The benefits of supplemented oxygen therapy have been reported in Chapter Two of this thesis.

Each week, each participant received verbal feedback on their progress in the intervention, the following weeks PRP prescription was negotiated with the participants to ensure the candidate, and study participants had similar outcome expectations. This negotiation was a critical aspect in the intervention design. A basic premise of this intervention was that the process

was as important as the content. Efficacy enhancing strategies as previously reported (Murphy et al., 2005) were incorporated to ensure optimal uptake and maintenance of healthy behaviours.

Equipment purchases required to implement the PRP included; pulse oximeters (Massimo Corp., Irvine, CA USA), treadmills (Landice pro sports trainer Version 1, NJ USA), an exercise bicycle (Monark Cardiocare 827E, Sweden), PVC covered hand held weights (Rebel sports home brand). Oxygen flow metres, disposable tubing and large E sized cylinders were also purchased. All motorised equipment purchased was sent to Hospital A's Biomedical engineering contractor for registration and certification of safe working order prior to patient use. Emergency equipment purchased included a latex free Air –Viva, a Venturi portable oxygen and suction unit, ampoules of saline, disposable nebulizers and, barley sugar. One metre squared sized posters with affirmative statements "move it or lose it", "there are 4 million Australians with COPD you are not alone" and tranquil ocean and rainforest scenes were procured for display in the PRP gymnasium. A whiteboard measuring two by three metres was purchased to graph the distance walked by participants each week on the treadmill by time, acceleration and incline.

The gymnasium equipment was organised as a circuit to optimise flow through the equipment. The stationary bicycles were arranged to enable the user to gaze out of the window. The whiteboard was wall mounted in a position that was visible to participants on the treadmills. The hand weights were arranged near the confectionary jar, this ensured weight training became a social part of the PRP.

All PRP graduates were awarded a certificate of attendance. For the purposes of this analysis, successful completion of this intervention was deemed attendance at 9 out of 12 PRP sessions.

4.5.3 Intervention C: Maintenance PRP

The weekly maintenance PRP (PRP+ m) was conducted for sixty minutes each week for eighteen weeks until the week 26 assessments. The outcomes from the week seven ISWT assessments determined the speed set for the treadmill in the maintenance program. The PRP prescription followed the same format as the six-week PRP intervention with the frequency, intensity and duration adjusted to the patient's capacity and progress.

4.6 Assessment Instrumentation

4.6.1 Demographic data

The demographic characteristics were obtained using a modified version of the Australian Nursing Alternative Documentation Assessment tool: (Appendix 9). This utility of this tool in rehabilitation programs has previously been reported (George, 1995). Additionally, at each assessment the following parameters were also recorded: Time, date, current medications; particularly any variation in respiratory medication or oxygen therapy usage, chest auscultation and outcome expectations.

4.6.2 Functional Assessment

Dual measures of functional status were evaluated in this project. The utility of these methods was reported in section 2.3.2 of this thesis.

4.6.2.1 Functional Capacity.

The ISWT (Singh et al., 1992) has been reported as a valid (Dyer et al., 2002; Payne & Skehan, 1996; Singh et al., 1994; Singh et al., 1992), reproducible test (Booth & Adams, 2001; Singh et al., 1994). It is reported as a field test of functional capacity that is sensitive to change in COPD (Bott & Singh, 1998) and, with other chronic conditions (Booth & Adams, 2001; Payne & Skehan, 1996). The MCID has yet to be reported in a peer-reviewed journal.

The ISWT course was established in the corridor adjacent to the conference rooms at Hospital A. The environment was kept as free from distraction (Solway et al., 2001) and as consistent as possible (Steele, 1996) to ensure results were reproducible and not influenced by test conditions. The same 30-metre tract was used for each assessment. Participants who usually employed a gait aid, were assessed in the ISWT with this aid. The use of a gait aid in timed walking tests has been demonstrated to increase measures of functional capacity (Probst et al., 2004; Solway et al., 2002).

The instructions for the ISWT were played to the study participants before each assessment. The walking test was played on a portable compact disc player and the volume was checked with each participant to ensure it could be easily heard from both ends of the 10-metre course. The acceleration required in the walking test was dictated by the timed signal. Progression to a new level in the ISWT is indicated by three beeps. Upon hearing this all subjects was informed "this level is faster than the last one". No encouragement was given throughout the walking test. The test ended when the subject was too dyspnoeic to continue, was not at the next cone before the next signal, attained of 85% of the predicted maximal heart rate or, was too exhausted to continue. The second test was repeated following a 20-minute rest (Singh, 1992). COPD participants aged greater than seventy years of age do not require a 'practice walk' in addition to two walks if they appear to be coping with the walking test requirements (Dyer et al., 2002). This modified protocol was employed in this project.

Participants who desaturated below 85% on exertion (as measured by pulse oximetry, see below) ceased their walking test and recommenced following a 20-minute rest with supplemented continuous intra nasal oxygen therapy (INO_2). These participants proceeded to undertake two ISWTs with continuous INO_2. Thereafter, each assessment was performed with the same amount of continuous intra-nasal oxygen. The INO_2 was supplied from a large (size E) stationary cylinder with a 12 metre connection of oxygen tubing as participants who are required to carry/ wheel an oxygen cylinder reduce their walking time (Snider, 2002).

The greatest distance covered in the ISWT, measured in metres, was taken as the test value for all participants. A variation between walks of greater than ten percent necessitated a third walk and, the results were averaged. Exercise prescription for treadmill activity was formulated from this test value.

All ISWTs were conducted under the supervision of a nurse accredited in basic and advanced cardiac life support as recommended in the ATS / ACCP guidelines (ATS / ACCP, 2003). All participants were continuously monitored through out their walking tests via pulse oximetry. A Masimo Set Radical (MSR) 2000 signal extraction pulse oximeter (Masimo Corporation, Irvine CA USA) was the instrument used for ISWTs. The MSR continuously displayed values for peripheral saturation, heart rate, plethysmographic waveform and signal quality. The MSR 2000 pulse oximeter had been reported as a reliable and valid instrument with low perfused peripheries. The signal box filters venous peripheral data from the signal and, displays only the arterial peripheral saturation on the screen. Arterial SaO_2 between 70-100% $\pm$ 1 standard deviation, in an operating temperature of 5-40 degrees Celsius were verified against a Biotek Index 2 and Masimo's simulator (Corporation, 2000)

The MSR 2000 pulse oximeter weighed 0.59 kilograms; this was therefore carried by the assessor during the ISWTs. The pulse oximeter probe was attached on a long cord. Participants were instructed that the assessor carrying the pulse oximeter would walk behind them so as not to pace them, and this method would eliminate any potential bias in their performance. The long cord provided sufficient room for participants to walk at their own pace and not near the assessor.

4.6.2.2 Functional Performance.

All study participants at Hospital A were fitted with a pedometer for the six-week duration of the intervention. Justification for the six week duration required for wearing a pedometer was reported in Section 2.3.2.2 of this thesis. Pedometers were worn on the belt or waistband in the midline of the thigh on either side of the body, consistent with the manufacturer's recommendations.

Previous studies have reported that there was no statistically significant difference in outcomes depending on which side of the body the pedometer is worn (Schneider et al., 2004).

Each participant was required to walk two set 10 metre distances and this process averaged their stride length. Stride length as measured in centimetres was then entered into the memory of the pedometer by the candidate to calculate distance (kilometres) walked. Results from the pedometers were recorded weekly in distance and steps walked and entered into an Excel spreadsheet to measure change over time and to compare mean differences between groups. The *Aussie Fit Sports Science* (Queensland, Australia) brand was the pedometer model purchased. This brand was an Australian designed pedometer that had recessed buttons to ensure data integrity. In addition, the PRP intervention group completed an exercise diary: (Appendix 4).

4.6.3 Symptoms

4.6.3.1 Dyspnoea.

The British Medical Research Council (MRC) Dyspnoea Scale (Fletcher, 1960) is a scale comprised of five written descriptors of situations of mobility that may induce dyspnoea: (Appendix 7). This measure has been reported as a valid (Ando et al., 2003; Bestall et al., 1999; de Torres et al., 2002), reliable (Garrod, Marshall, Barley, & Jones, 2006; Wedzicha et al., 1998) and responsive (Ando et al., 2003; de Torres et al., 2002) measure with respiratory conditions and/or following an intervention such as PRP participation. This scale is easy to use, can be completed in one minute and, is similar in nature to the New York Heart Association's cardiac status scale (Frith, 2002). Convergent validity has been established with the symptoms subscale of the St George Respiratory Questionnaire (Jones, Quirk, Baveystock, & Littlejohns, 1992). The suggested MCID has been reported as a reduction in score by one grade in this measure (Nosworthy et al., 2001).

4.6.3.2 Mood status.

The Hospital Anxiety & Depression Scale (The HAD) is a 14 item questionnaire (Zigmond & Snaith, 1983). Seven questions are allocated to both anxiety and depression: (Appendix 8). The scale can be completed in two to six minutes (Hermann, 1997). The HAD was designed for use in the outpatient setting (Snaith, 1987). Validity in the non-psychiatric setting has been reported (Hermann, 1997; Snaith, 1987; Spinhoven et al., 1997; van Ede et al., 1999; Zigmond & Snaith, 1983). Convergent validity in the inpatient rehabilitation setting (Vedana et al., 2002) and with COPD and other chronic health conditions has been established (Quintana et al., 2003). The HAD has been reported as sensitive to change during the course of the disease and in response to treatment (Hermann, 1997). The test and retest reliability in The HAD has been reported with a Cronbach alpha of 0.86 for the anxiety scale and, 0.86 for the depression scale (Quintana et al., 2003). Each of the 14 questions is scored from zero to three. Each subscale for anxiety and depression can be reported separately. A score < 8 in each subscale equates to no evidence of anxiety or depression, < 11 as probable anxiety or depression, scores > 14 indicate severe anxiety or depression (Hermann, 1997; van Ede et al., 1999; Zigmond & Snaith, 1983). The clinical important difference has been reported as a change in score by 2 points (Zigmond & Snaith, 1983).

4.6.4 Health Related Quality of Life

The St George Respiratory Questionnaire (SGRQ) (Jones, Quirk, & Baveystock, 1991) is a disease specific 76 item questionnaire that takes approximately 10 minutes to complete. This instrument has three components that seek to quantify Symptoms, Activity and Impacts measured in a patient with a static or reversible respiratory condition over the longer term: (Appendix 10).

The Symptoms component reports on cough, wheeze, dyspnoea, sputum production and the frequency and duration of exacerbations. Responses are selected on a five point Likert scale. The Activity component examines

physical activities that are limited by dyspnoea. The Impacts subscale evaluates the effect that the respiratory ailment has on employment, medications, isolation, health expectations and daily living. These latter two subscales require a dichotomous response.

The SGRQ has been reported as a valid (Jones et al., 1992), reliable (Seemungal et al., 1998) and responsive measure (Finnerty, Keeping, Bullough, & Jones, 2001; Osman et al., 1997). Convergent validity for each of the three subscales has been established (Jones et al., 1992). The SGRQ has been reported as sensitive to change when used in long term evaluations and, predictive of health resource use in people with COPD (Osman et al., 1997; Seemungal et al., 1998).

Each subscale/section in the SGRQ is scored separately and each question is weighted. The weights attached to each question were validated in a multinational study (Quirk et al., 1991). The final score from the three sections are aggregated and may range from zero to one hundred. Zero equates to no impairment in HRQoL. The MCID is reported to be four units (Jones et al., 1991; Schunemann et al., 2003).

The Assessment of Quality of Life (The AQoL) is an Australian developed generic self administered HRQoL measure (Hawthorne et al., 1999). Validity and reliability has been established (Hawthorne et al., 1999). Convergent validity and responsiveness to treatment was reported in a randomised controlled trial of older Australians (median age 77$\pm$ 9 years) in the outpatient setting when compared with, the SF-36 and the OARS scales (Osborne et al., 2003).

The AQoL comprises 15 questions of five domains, with three questions in each area. These domains are Independent living, Social relationships, Physical senses, Psychosocial wellbeing and Illness: (Appendix 11). Each question has the option of four responses, which are ranked from optimal to worse health. The measure's internal consistency has been reported as a Cronbach alpha of 0.81 with overall reliability as 0.73 (Hawthorne et al., 1999). The instrument generates a single final score with a high score

reporting a poorer HRQoL. The weights associated with the questionnaire responses have been validated from longitudinal follow up thus, supporting its utility with chronic health conditions (Hawthorne, Osborne et al., 2003).

The AQoL is used in cost utility evaluations to elicit patient preferences (Osborne et al., 2003). A number of population specific mean reference values have been reported (Hawthorne & Osborne, 2005). In an outpatient setting, a value of 0.63 (95%CI 0.60 - 0.63) has been reported as the mean normative value (Hawthorne, Richardson, & Day, 2001). A value of 0.06 has been reported as a clinically important difference in utility evaluations (Hawthorne & Osborne, 2005).

4.6.5 Self Efficacy

Self - efficacy is usually measured specific to the situation. At present, there is only one published disease specific self-efficacy questionnaire (Wigal et al., 1991). Anecdotal evidence from pulmonary rehabilitation coordinators within Australia suggested that it did not tap into areas of importance in their aged population group and was therefore discontinued.

This project sought to find a self-efficacy questionnaire that would accommodate both distinct interventions. In the absence of a suitable measure, The General Self Efficacy Scale (GSES-12) was administered. Generalized self efficacy has been described as a global confidence to cope across a range of situations (Barlow, Williams, & Wright, 1996). The GSES-12 seeks to measure three domains: initiative, effort and persistence (Sherer, Maddux, Mercandante, Prentice-Dunn, & Rodgers, 1982). The utility of this measure would be as an adjunct to measure for behavioural change (Sherer et al., 1982). The content of this measure has been reported as consistent with assumptions that the assessment of whether a task can be successfully accomplished will affect the outcome of the behaviour and, that mastery experiences are generalisable to new situations (Berarducci & Lengacher, 1998).

Initial validation of the instrument was with a broad population in the domains of social skills and vocational competence (Sherer et al., 1982). Construct reliability was measured with a cronbach alpha of 0.86 when compared with the Mastery scale and a self esteem scale (Woodruff & Cashman, 1993). The GSES-12 is probably a measure of domain self efficacy as compared to general or task efficacy (Woodruff & Cashman, 1993). The GSES questionnaire had been evaluated for use with older adults and, revised from a 17 to 12 question measure (GSES-12) (Bosscher & Smit, 1998): (Appendix 12). The GSES-12 has been reported to be internally consistent with a Cronbach alpha 0.69 and within each subscale a cronbach alpha >0.63. The inter-item correlations varied between 0.16 – 0.38. This outcome was reported as consistent with a broad construct as these results were <0.4 (Bosscher & Smit, 1998). Responses are selected from a five point descriptor scale ranging from strongly disagree to strongly agree. The 12 questions are scored from 1 to 5 with a maximum score of 60 units (Woodruff & Cashman, 1993). Higher scores articulate with greater self-efficacy.

4.7 Data recording strategy

All data collected were input into a password protected Access database. This database was created with the assistance of a senior software programmer at Hospital A which we have reported (Kenyon et al., 2004). Accuracy of the data input into the database was ensured by data input by one and checked by another.

This project was reviewed and approved by both the Human Research and Ethics Committee of Hospital A and the University.

4.8 Data Analysis

4.8.1 Statistical analysis

Statistical analysis was performed using SPPS Version 12.02 for windows (SPPS Inc. IL USA). A master copy was formulated and a copy made to run

the analysis. Each week a set run of queries was made on the master and copy version to ensure both produced identical answers and thus the working copy had not been corrupted.

4.8.1.1 Validation of data.

Descriptive statistics were calculated for all results. The data were examined to determine if the distribution of the results were significantly different to a normal distribution. A skewness statistic between –1.0 and not greater than +1 or, when the mean and median are equivalent suggests, the distribution is not significantly different from a normal distribution.

Chi square statistics and analysis of variance were calculated to identify any baseline group differences in the data defined as categorical and continuous variables respectively. The data were further examined to verify homogeneity of variance. When groups of unequal size are compared, it is critical that there is homogeneity of variance (Pett, 1997). The Levene's test for homogeneity of variance was used to confirm that there was no statistically significant difference between the three intervention groups in the dependent variables that were evaluated: (Table 4.2).

Table 4.2 Instruments to evaluate the study's dependent variables

Dependent Variable	Outcome measure	Indications of improved health would include:
Functional status	Incremental Shuttle Walking Test	Increased metres walked
	Pedometers	Increased metres and or steps walked
Symptom control	MRC Dyspnoea Scale	Reduced grade on scale of 1 to 5
	The Hospital Anxiety & Depression scale	Reduction in score on scale that ranges from 0 to 42
HRQoL	The St George Respiratory Questionnaire	Reduction in score on scale that ranges from 0 to 100
	The Assessment of Quality of Life	Reduction in score on scale from 0 to 45
Self efficacy	The General Self Efficacy scale	Increased score on scale that ranges from 12 to 60

4.8.1.2 Hypothesis Testing.

To evaluate and compare the effect of participation in a six-week intervention normally distributed data were compared with two-way analysis of variance (ANOVA) or, two way repeated measures and univariate ANOVA and were expressed as mean and standard deviation unless otherwise stated.

Mauchley's test of sphericity was examined when repeated measures and univariate ANOVA was used. When Mauchley's test was statistically significant at the 0.05 level, the epsilon correction (Greenhouse-Geisser) was reported.

Post hoc Scheffé tests were used when there were more than two groups for comparative analysis. The Games-Howell post hoc test was substituted when the Levene's statistic was significantly different at the 0.05 level (Morgan, Leech, Gloeckner, & Barrett, 2004).

Pairwise comparisons with non-normally distributed data were examined using the Mann-Whitney U statistic. Correlations were then calculated with the Spearman rho statistic. A Friedman test was conducted to examine if there were differences among the mean ranks of the six-weeks in pedometer data. Orthogonal contrasts were performed using Wilcoxon tests with significance adjusted for multiple comparisons (Bonferroni) when appropriate. Corresponding descriptive statistics are expressed as medians and interquartile ranges unless otherwise specified. Statistical significance was set at $\alpha = 0.05$.

The effect size was calculated (*d*) to "translate changes in health status into a standard unit of measurement that will provide a clearer interpretation of results" (Benzo, Flume, Turner, & Tempest, 2000 ,p.232). Unless otherwise stated, *d* was expressed in standard deviation units using the following formula:

$$d = \frac{M_A - M_B}{\sqrt{SD_A^2 + SD_B^2}/2}$$ (Morgan et al., 2004).

Alternatively, the Pearson correlation coefficient (*r)*, multiple correlation (R) and eta (η) were calculated when appropriate. The calculated effect size was then compared against guidelines of effect size measures (Cohen, 1988).

When possible, a comparison of the primary results achieved with the known minimally clinically important difference (MCID) was made to determine if the results were clinically important and not simply statistically significant. The minimal clinically important difference (MCID) had been defined as:

> "the smallest difference in score corresponding to the smallest difference perceived by the average patient that would mandate, in the absence of troublesome side effects and excessive cost, a change in patient management" (Jaeschke, Singer, & Guyatt, 1989 ,p.408).

In addition, the following tests were used for hypothesis testing of week 52 data analysis. A mixed multivariate analysis of variance (MANOVA) was used to assess whether there were differences in dependent variables by gender and allocated group over repeated measures of time with normal preliminary assumption testing conducted. To examine relationships between variables, univariate correlations and multiple regression analysis was used to determine what features are predictors of improvements in each outcome measure at week 52. The dependent variable for the multiple regression analysis was the project's subset of participants who had achieved the MCID in the outcome of interest. Preliminary assumption testing was undertaken to ensure that the subset data was normally distributed.

4.8.1.3 Costs of care.

A cost-utility analysis (CUA) was undertaken to account for the costs incurred by the service provider and, the health preference state (Quality Adjusted Life Years) reported by the project's participants. The formula to calculate QALYs and the incremental cost effectiveness ratio was reported in section 2.4.1 of this thesis as follows:

$$\text{ICER} = \frac{\text{Costs (intervention group)} - \text{costs (control group)}}{\text{QALYs (intervention group)} - \text{QALYs (control group)}}$$

Two methods were utilised to generate a cost utility ratio from the study data. The primary CUA is modelled on the study data. To model the CUA beyond the duration of the study to the lifetime of patients, life expectancy and life time costs are calculated using data from published reports (Higgins, 2003; Kuntz & Weinstein, 2001). An annual mortality rate for the mean age for the control and intervention group was determined from Australian life tables (Australian Bureau of Statistics, 2003) and adjusted for gender differences within each group.

All participants who completed the six-week interventions were included in the costs of care analysis. The intervention costs per person were calculated on the intention to treat basis. Intention to treat requires all participants who were enrolled in the study to be accounted for and reduces bias in presenting results that exclude non completers (Heritier, Gebski, & Keech, 2003)**.**

All study participants had their inpatient medical files reviewed for unplanned hospital admissions and emergency room visits which were screened by diagnostic coding – ICD-10 (Organization, 1998). Average bed days costs were calculated in accordance with the Victorian Department of Health Services costs.

Mortality data was sourced from a medical records review. Whether the deceased was an inpatient or an outpatient, the date and circumstances were recorded. Identification of the cost of resources and the source of the valuations used in this study were recorded in 2004 Australian dollars: (Table 4.3-4.4)

Table 4.3 The valuation of the Direct Costs

Resource	Unit Cost	Source of valuation
Prescription medications Private prescriptions	Note [1]	Schedule of Pharmaceutical Benefits August 2004, Australian Government Dept of Health and Aging: Canberra Health Insurance Commission & PBS database: Canberra Patient's Health Care & community resource utilization diary
Hospital outpatient visits:		
Respiratory Physician	$A 272[2]	Victorian Metropolitan Health & Aged Care
Other	$A 171.50[3]	Services Directory
		2004.www.health.vic.gov.au/pfg2004
Emergency Department presentations	$A350[4]	Director of ED, Hospital A
Hospital admissions:		
E64A	$A4694.63[5]	WEIS-12 2004-05 Victorian Cost weights
E64B	$A2629.98	Victorian Metropolitan Health & Aged Care Services Directory 2004.
Intervention costs		
Salary: candidate	$A 10.70/hr	www.health.vic.gov.au/pfg2004
Salary + 10% on costs		Human Resources, HOSPITAL A
Physio. Gr 2 Yr 4 EFT 0.1	$A 33.21/hr	
Capital costs		Human Resources, HOSPITAL A
Treadmills Landice V1.0 x2	$A10455 each	Purchase costs – Australian distributor
Exercise Bike Monark cardiocare 827E	A1550	Purchase costs – Australian distributor
Hand weights 0.5-2kg	$A80	Purchase costs – Rebel sports store,
Whiteboard: gymnasium	$A780	Purchase costs – HOSPITAL A Supply Dept
Massimo Radical 2000 Pulse Oximeter x3	$A3762 each	Purchase costs – Parke Davis Australian distributor
TEAC CD /cassette player	$A129	Purchase costs – KMART
Incidentals		
Disposable nasal prongs	$A0.20 each	Purchase costs – HOSPITAL A Supply Dept
Room Hire (CDSMP program)	$A40/hour	Education Dept- HOSPITAL A
Catering (CDSMP program)	$A11.60/pp/program	Food services receipt –HOSPITAL A
Car parking	$A2.75pp/attendance	Purchase costs -Wilson car parking
Pedometers	$A49.99 each	Purchase costs-Rebel sports store,
Hospital Volunteer drivers	$A0.63/km	Purchase costs-Social Work dept, HOSPITAL A
Photocopying exercise diaries	$A0.07/page	Purchase costs – HOSPITAL A Supply Dept
Reference text (CDSMP)	$A38.00 each	Purchase costs – Arthritis Victoria
Leader training (CDSMP)	$A330.00 pp	Purchase costs – Arthritis Victoria

1 Notes to support Table 4.3.

2 Outpatient visits: respiratory physician consultations

3 Outpatient visits: mean cost for general medical visits.
4 This cost was provided by the Director of HOSPITAL A's ED as the mean cost of ED presentations calculated in 2004. There remains no formal costing for ED attendance by medical condition in Victoria, Australia
5 Discharge codes: E64A**:** exacerbation of COPD with complications,

Table 4.4 Identification and valuation of indirect and intangible costs

Resource	Unit Cost	Source of valuation
Indirect costs		
Co payment prescription drugs for Social Security recipient	$A3.50	Schedule of Pharmaceutical Benefits August 2004, Australian Government Dept of Health and Aging: Canberra
Medications: co-morbidities Complimentary therapies, medications/supplements Private prescriptions		Schedule of Pharmaceutical Benefits August 2004,Australian Government Dept of Health and Aging: Canberra Health Insurance Commission & PBS database: Canberra Patient's Health Care & community resource utilization diary
Loss of productivity due to disease process or, the Interventions Carer loss of productivity due to carer burden		Not considered in this analysis as all but two participants received Aged Pensions
Intangible		
HRQoL	QALY	Assessment of Quality of Life
Reduction in Symptoms		SGRQ

Chapter Five Results

This chapter is comprised of four sections:

Section one compares the results from participation in the six-week interventions (Intervention A and B) and the control group at week seven on functional status, symptom control, HRQoL, and self-efficacy.

Section two examines the longitudinal outcomes of intervention A, B and the control group until week 52 and, the impact of a structured weekly maintenance exercise program i.e. PRP+m (Intervention C) following pulmonary rehabilitation attendance.

Section three evaluates the costs of care.

Lastly, section four reports on the recording of adverse outcomes.

5.1 The Cohort

5.1.1 Participant's details

5.1.1.1 All those screened.

This study began in February 2002 and participant recruitment continued for twenty-two months. During that time 1217 patients were admitted to Hospital A with an exacerbation of COPD. Seven hundred and twenty six patients (60%) were male. These patients had a mean age of 71 years (median: 73 years; range: 43-91 years). During this period of recruitment, 252 patients (54% males) with a mean age 71 years (median: 72 years; range: 47-93 years) were referred to pulmonary rehabilitation by a health clinician at Hospital A or, via self-referral. Independent t tests confirm that there was no significant difference by gender (P = 0.16) in those referred to pulmonary rehabilitation when compared to all those admitted to Hospital A. The equivalent referral by gender at Hospital A is in contrast to publications that report more men than women are referred to a cardiac rehabilitation program (Harlan et al., 1995; Hellman & Williams, 1994)**.**

All referrals were screened to determine whether they met study inclusion criteria. There were 186 (74%) referrals that fulfilled the inclusion criteria. All referrals that fulfilled the inclusion criteria were contacted. Ninety-seven (52%) people agreed to participate in the study. Sixty-four (34%) people who

had met study inclusion criteria declined to participate. A further 25 (14%) people fulfilled the inclusion criteria but experienced barriers to participation: (Table 5.1).

Table 5.1: Summary of referrals not included in the study

Group	*n*	Sub group	*n*	Gender	*n*
Not meeting inclusion criteria	66				
		Illiterate in English	28	Male Female	19 9
		Unstable cardiovascular co-morbidity	11	Male Female	10 1
		Unstable respiratory condition	9	Male Female	4 5
		Diagnosis by spirometry not COPD	7	Male Female	0 7
		Documented cognitive impairment	6	Male Female	5 1
		Receiving Renal dialysis	3	Male Female	3 0
		Mobility Limitation due to arthritis	2	Male Female	0 2
Met inclusion criteria					
Not interested	64			Male Female	28 36
Fulfilled the inclusion criteria yet unable to participate	25				
		Participants without transport	12	Male Female	7 5
		Deceased within five weeks of referral	6	Male Female	4 2
		Un-contactable	5	Male Female	2 3
		Local doctor advised PRP was not necessary	1	Male Female	1 0
		Primary carer without respite care	1	Male Female	1 0

A flow chart was constructed that follows the recommendations of the Consolidated Standards for Reporting of Trials (CONSORT) statement (Begg et al., 1996; Moher, Jones, & Lepage, 2001). The Consort provides a concise, transparent means of reporting study enrolment, group allocation, follow up and analysis in randomised parallel designed studies (Altman et al., 2001). This flow chart summarises all those screened at Hospital A for study inclusion, the number randomised to an intervention and the number who were

re-assessed at week 7. As depicted, there were few who did not receive the intervention or were lost to follow up: (Figure 5.1).

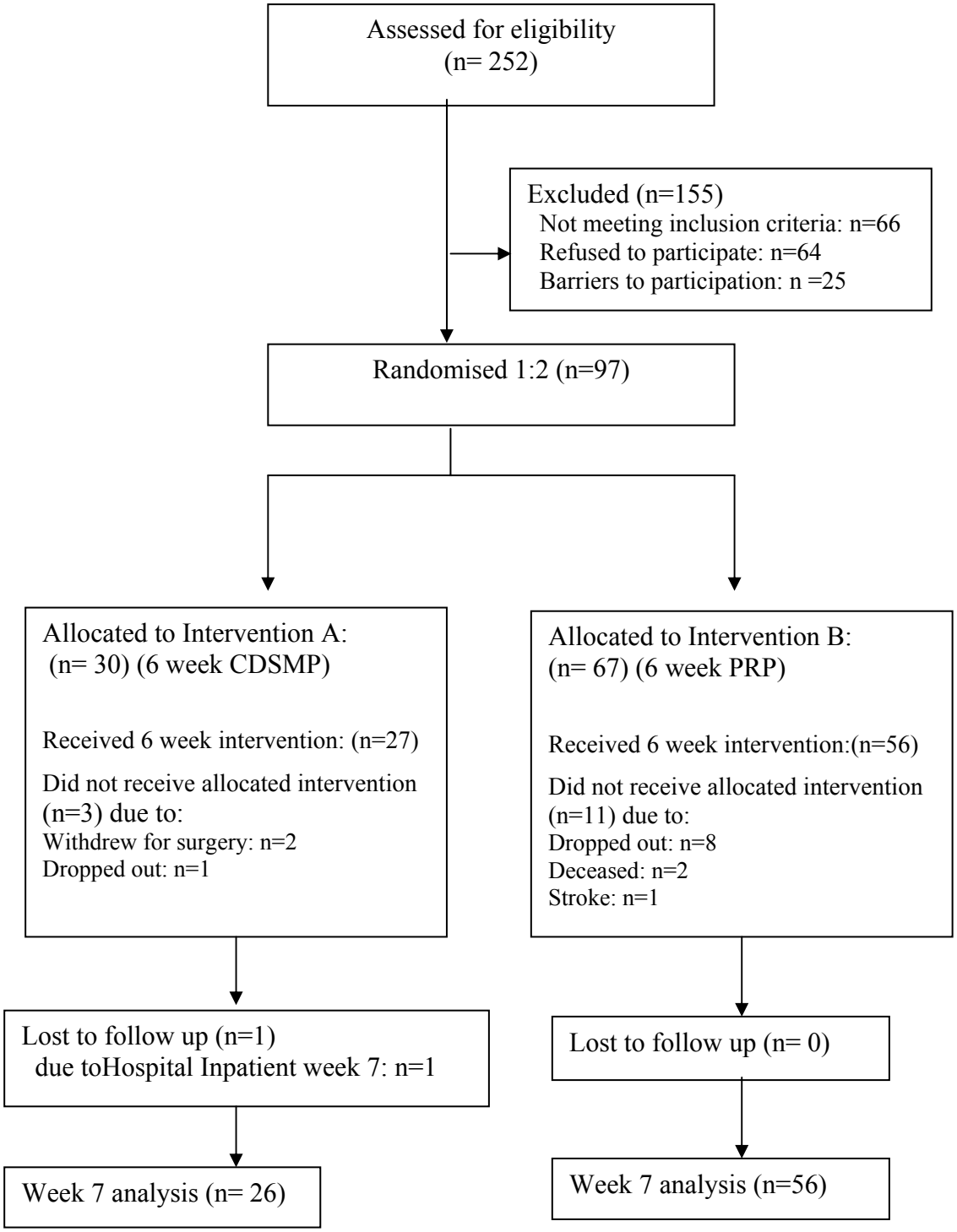


Figure 5.1: Flow chart of study referrals, randomisation and post program follow up at Hospital A.

The demographic profiles of the catchment areas served by Hospital A and B were examined in Chapter One. The baseline clinical and demographic characteristics of the study participants by Hospital were compared. The only significant differences between participants from Hospital A and B were evidenced in Functional Vital Capacity and smoking status ($P<0.01$). Hospital A's cohort reported a few participants who were still smokers despite the participant's awareness of the deleterious effects this had on their lung function. Hospital B's greater FVC suggests a higher likelihood of lung hyperinflation. Both results point to poor lung health: (Appendix 13).

5.1.1.1.1 THE EXPERIMENTAL GROUP AT HOSPITAL A

The 97 participants who satisfied the inclusion criteria and gave informed consent formed the final experimental group at Hospital A. Fifty one percent of the group was male. The mean age of the sample was 68 years
(SD: 9; range: 39-87 years) as compared to the age of all eligible participants screened: mean 71 years (SD: 11; range: 47-93 years).

During the recruitment period, 60% of all COPD admissions to Hospital A were male; which is consistent with the proportion of Australians diagnosed with COPD by gender (3 males: 2 females) as reported by the AIHW (2002). However, as reported in Chapter One, a four year audit (1998-2001) at Hospital A of COPD admissions revealed a population that was 50% male. This study sample at Hospital A by gender, is consistent with the four year audit.

The baseline clinical characteristics of each group were compared. There were no statistically significant differences found between these intervention groups in clinical detail. These data have been tabled as either categorical: (Table 5.2) or continuous data: (Table 5.3). Lung function results have been presented as both the directly measured (actual) value and as a percentage of predicted normal for age, sex, height and weight. The latter value possibly presents the more useful data. The smoking status of participants did not change through out the study. Despite encouragement from the candidate and fellow study participants, to adopt a smoking cessation strategy, no smoker in the study would consider quitting. Although there were some individual

variations between groups, post hoc Scheffé tests report the only statistically significant baseline difference were the Functional Vital Capacity (FVC) (actual and predicted %), between the experimental and control groups:(Table 5.3).

Table 5.2: Summary of baseline clinical characteristics by group i

	CDSMP (%)	**PRP (%)**	**CONTROL (%)**	**χ^2 statistic**	**P value**
	N=30	N=67	N=23		
Subjects (male)	15 (50%)	35 (52%)	15 (63%)	0.71	0.70
Australian born	20 (67%)	44 (66%)	16 (67%)	0.23	0.89
COPD Severity [A]				2.36	0.67
Mild	1 (3%)	2 (3%)	1 (4%)		
Moderate II A	8 (27%)	20 (30%)	3 (13%)		
Moderate II B	11 (37%)	24 (36%)	9 (37%)		
Severe	10 (33%)	21 (31%)	11 (46%)		
Long Term Oxygen Therapy ($LT0_2$)	8 (27%)	14 (21%)	4 (17%)	1.44	0.84
Never Smoked	3 (10%)	6 (9%)	0 (0%)	2.34	0.31
Current Smokers	3 (10%)	7 (10%)	0 (0%)	3.46	0.18
Former Smokers	24 (80%)	54 (81%)	23 (100%)	2.62	0.27

Note [A] GOLD Classification

Table 5.3: Summary of mean baseline clinical characteristics by group ii

	CDSMP M (SD)	**PRP M (SD)**	**CONTROL M (SD)**	**Value F**	**Between Group Differences (Scheffé)**
$LT0_2$Hours per day	7.4 (5.1)	13.3 (7.3)	18 (7.1)	3.91	---
$LT0_2$ Litres *(l)* per minute	0.6 (1)	0.5 (0.9)	2.0 (0.7)	0.19	---
FEV_1 *l* Actual	1.02 (0.6)	1.01 (0.5)	0.88 (0.46)	0.69	---
FEV_1 $l_{\%\ Predicted}$	42.5 (23.8)	42.5 (18.7)	36 (16)	1.08	---
FVC *l* Actual	2.3 (0.7)	2.3 (0.8)	1.63 (0.68)	7.65*	PRP & CDSMP > Control
FVC $l_{\%\ Predicted}$	74.5 (16.9)	74.8 (17.9)	52 (15)	16.75**	Control< PRP & CDSMP
TLCO Actual	10.8 (6.3)	9.9 (5.1)	N/A		---
TLCO % Predicted	48.4 (19.5)	43.1 (18.2)	N/A		
Smoking History Pack Years	35 (25)	42 (27)	51 (20)	2.51	---
Age (years)	67.8 (6.8)	68.4 (10.1)	70.3 (6.9)	0.55	---
Co-Morbidities	1.7 (1.2)	1.7 (1.2)	2.3 (1.4)	1.34	---
Height (m)	1.67 (.07)	1.63 (.08)	1.65 (11)	0.45	
Weight (kg)	76 (17)	72 (22)	69 (15)	0.10	
B M I (kg/m^2)	28.9 (6.0)	27.4 (6.1)	25 (14)	0.10	

Note: N/A Not Available *p<0.05 **p<0.001 M mean SD standard deviation

The demographic details of the three groups were summarised: (Table 5.4).

Table 5.4 Details of participants

	CDSMP	**PRP**	**Control**
	N=30	N=67	N=23
Primary carer	0	8 (12%)	0
Living arrangements:			
With Spouse	20 (67%)	38 (57%)	12 (52%)
Family Members	3 (10%)	10 (15%)	1 (4%)
Others	3 (10%)	1 (1%)	0
Alone	4 (13%)	18 (27%)	10 (44%)
Residence:			
House Owner	29 (97%)	61 (91%)	N/A
Rental Accommodation	0	5 (7%)	N/A
Supported Accommodation	1 (3%)	1 (2%)	N/A
Prior PRP attendance	7(23%)	8(12%)	N/A
Highest Level of Education:			
University	3 (10%)	3 (4%)	N/A
Trade Certificate	1 (3%)	15 (22%)	N/A
High School	25 (83%)	44 (66%)	N/A
Primary School	1 (3%)	5 (8%)	N/A
Past Employment:			
Skilled	18 (60%)	36 (54%)	13 (56%)
Unskilled	9 (30%)	24 (36%)	10 (44%)
Homemaker	3 (10%)	7 (10%)	0
Income:			
Employed	0	1(1%)	0
Spouse	5(17%)	3(4%)	0
Govt Pensions:			
Aged	24 (80%)	53 (79%)	23 (100%)
Disability	0	1 (2%)	0
Veteran's	1 (3%)	8 (12%)	0
Unemployment	0	1 (2%)	0

Note: N/A: Not Available

All participants who did not complete the six-week intervention were accounted for: (Figure 5.1). Their baseline characteristics were examined and 64% had a BMI above the normal limits, 43% continued or resumed smoking: (Appendix 14).

5.2 Week Seven Findings

5.2.1 Indicators for disease progression in COPD

5.2.1.1 Functional Assessment.

5.2.1.1.1 FUNCTIONAL CAPACITY

There were a statistically significant difference in the ISWT baseline results between the experimental groups and the control group as measured by a one way ANOVA: F (2,101)=8.92, P<0.01. Post hoc Scheffe's test reports the intervention groups were a homogeneous set at baseline (P=0.98) and the control group was significantly different at baseline: (Table 5.5).

Table 5.5: Summary of mean ISWT results by allocated group shown in distance walked in metres

	CDSMP	PRP	CONTROL	Value		Between Group Differences
	M (SD) Range	*M (SD)* Range	*M (SD)* Range	*F*	P	(Scheffé)
Baseline	173 (99) 30-340 *m*	178 (100) 30-390 *m*	288 (149) 50-650 *m*	8.92	<0.01*	Control > both Experimental Groups
Week 7	208 (118) 10-460 *m*	242 (98) 40-470 *m*	244 (169) 20-660 *m*	0.77	0.47	Nil [a]

Note: *p<.05 [a] Games-Howell

The within group results were examined by a paired t test, these results were summarized: (Table 5.6).

Table 5.6 Within Group ISWT summary results showing mean distance walked in metres

	Baseline	**Week 7**	**Value**		
	M (SD) Range	*M (SD)* Range	t	P	*n*
CDSMP	173 (99) 30-340 *m*	208 (118) 10-460 *m*	-3.02	0.01	*25*
PRP	178 (100) 30-390 *m*	242 (98) 40-470 *m*	-7.60	< 0.01	*55*
CONTROL	288 (149) 50-650 *m*	244 (169) 20-660 *m*	2.52	0.02	*22*

A two way ANOVA between the three groups was computed. There was no statistically significant interaction between allocated group and baseline ISWT results on week 7 ISWT results: F (23,37)=1.04, P=0.45. There was a significant effect of group allocation on week 7 ISWT results, F (2,37)=4.09,P=0.03. Eta for group allocation was 0.18, which is a small effect. There were a statistically significant improvement in the ISWT results between baseline and week 7: F (39,37)=8.40, P<0.01. Eta was 0.89 which articulates with a larger than typical effect size, according to Cohen's (1988) guidelines. The Games-Howell post hoc reported all three groups had become a homogenous set at week 7 (P= 0.52) as the intervention groups had improved and the control group were worse.

By week 7, the control group recorded a 15% (- 44 metres) downward trend in functional capacity. The small effect size (d=0.2) suggests that the overall clinical difference is unchanged in this group. The mean increase in walking distance in the ISWT by the PRP group was 64 metres or, 26% improvement from baseline. The mean increase in the ISWT for the CDSMP group was 35 metres or, 17% improvement. Improvement in functional capacity measured by walking distance for people with COPD following participation in a self-management intervention is this thesis's novel finding.

5.2.1.1.2. FUNCTIONAL PERFORMANCE

All participants at Hospital A were fitted with a pedometer for the duration of the six-week intervention. Functional performance as recorded by pedometers were included in the final analysis if participants wore their pedometers for the full six-weeks of the intervention or, data was recorded in five weeks and the median score of these weeks was inserted for the missing week in 11 of the 46 cases. The use of the median value of the pedometer data is a method that has been previously reported in a COPD study (Wood-Baker, McGlone, Venn, & Walters, 2006). There were no statistically significant differences in the functional performance as recorded in steps (P=0.15) and, kilometres (P=0.17) between participants in a pulmonary rehabilitation program as compared to the self-management program:(Table 5.7).

Table 5.7: Summary results of the weekly median distance in kilometres and steps walked, over the period of the six-week interventions as measured with a pedometer

Variable	**Group**	Median	*IQR1*	*IQR3*	Range	***n***	Mean Rank	Sum of Ranks	Mann-Whitney U Test	Z score	**P value**
Steps per week	**CDSMP**	149,501	68,378	265,793.5	7,241 – 338,125	*12*	27.67	332	142	-1.44	**0.15**
	PRP	87,725	51,235	154,545.5	6,845 – 368,568	*34*	21.30	703			
Kilometres per week	**CDSMP**	72.0	29.75	336.0	4.0 – 431.0	*12*	27.50	330	144	-1.39	**0.17**
	PRP	45.9	28.38	89.04	0.87-258.69	*34*	21.36	705			

5.2.2 Symptom control

5.2.2.1 Dyspnoea.

Dyspnoea was measured at baseline and at the post program assessment (week seven) with the British Medical Research Council's (MRC) Dyspnoea Scale. The baseline MRC Dyspnoea scores for the three groups were normally distributed: CDSMP (skewness=0.39), PRP (skewness =0.07) and the Control (skewness = -0.28). A one-way ANOVA reported no significant baseline differences between the three groups:(Table 5.8). The MRC Dyspnoea raw scores recorded by participants in each intervention group at baseline and week 7 were tabled: (Appendix 15).

Table 5.8: Baseline MRC Dyspnoea summary results as reported by grades*

	CDSMP M (SD) Range	**PRP** M (SD) Range	**CONTROL** M (SD) Range	Value F	P	n
Baseline	3.07 (0.83) 2 to 5	3.01 (0.79) 1 to 5	3.22 (0.67) 2 to 4	.58	0.56	120

Note: * The higher the grade (1-5) the more impact dyspnoea has on the person

A two way ANOVA was computed to evaluate the within and between group outcomes. A statistically significant improvement in dyspnoea was recorded: F (3,76)=5.39, P=0.002. Table 5.9 reports no statistically significant interaction between group and baseline dyspnoea grade for this outcome.

Table 5.9: Two way ANOVA for the MRC Dyspnoea Scale

Dependent variable: Week 7 Dyspnoea score	*df*	*MS*	*F*	η^2
Group Allocation	1	2.18	3.15	.01
Baseline MRC Dyspnoea Grade	3	3.74	5.39**	.18
Group Allocation* Baseline Dyspnoea Grade	2	.08	.12	0.003
Error	76	.69		

Note: **p<0.01

However, the PRP group was the only intervention to record a statistically significant reduction in dyspnoea: (Table 5.10). The control group did not record a dyspnoea grade at week seven and, this is a limitation of this finding.

Table 5.10: Within group MRC Dyspnoea grade mean summary results

Allocation	**Baseline** ***M (SD)*** Range	**Week 7** ***M (SD)*** Range	t	Value P	*n*
CDSMP	3.04 (0.82) 2 to 5	2.96 (0.96) 2 to 5	.42	0.66	*26*
PRP	2.95 (0.70) 2 to 4	2.50 (0.85) 1 to 4	3.83	< 0.001	*56*
CONTROL	3.22 (0.67) 2 to 4	N/M	---	---	23

Note: N/M not measured

In summary, the mean change in dyspnoea for the PRP group was an improvement of 0.5 of one grade. The mean change in dyspnoea grade for the CDSMP was an improvement by 0.1 of one grade. The minimal clinically important difference (MCID) in this measure was considered to be a reduction (i.e. improvement) in the report of dyspnoea by one grade (Nosworthy et al., 2001). Although a statistically significant outcome was reported in the PRP group, the result was unlikely to be a clinically important difference for this group.

5.2.2.2 Mood Status.

The baseline HAD Total Score for the CDSMP group (skewness=0.026), the PRP group (skewness=0.421) and the control group (skewness=0.21) were normally distributed. A one-way ANOVA indicated that there were no significant baseline differences in the total score and subscales anxiety and depression by allocated group: Table 5.11

Table 5.11: The HAD results by allocated group

Measure		CDSMP		PRP		CONTROL		Value
		n	*M (SD)* Range	*n*	*M(SD)* Range	*n*	*M (SD)* Range	F	P
Anxiety	Baseline	*26*	7 (4) 0 to 17	*56*	6 (4) 0 to 16	*23*	6 (4) 0 to 14	0.34	0.71
	Week 7	*26*	7 (4) 2 to 17	*56*	6 (4) 0 to 15	*23*	7 (5) 0 to 17		
Depression	Baseline	*26*	6 (3) 0 to 14	*56*	5 (3) 0 to 12	*23*	5 (3) 1 to 13	1.65	0.20
	Week 7	*26*	5 (3) 1 to 11	*56*	4 (3) 1 to 12	*23*	5 (3) 0 to 15		
∑ Score	Baseline	*26*	13 (6) 2 to 24	*56*	11 (7) 1 to 26	*23*	10 (6) 2 to 23	1.01	0.37
	Week 7	*26*	12 (5) 4 to 20	*56*	10 (6) 1 to 24	*23*	12 (7) 0 to 32		

As previously stated, a score ≥ 8 in either subscale in this instrument is considered to be indicative of a clinical manifestation of anxiety or depression (Zigmond & Snaith, 1983). Based on this criterion, eleven (42%) participants in the CDSMP, 26 (46%) in the PRP group and 9 (39%) Control participants were clinically anxious. Seven (27%) of the CDSMP participants, eleven (19%) participants in the PRP and four (17%) Control subjects were clinically depressed.

A two way ANOVA was undertaken to evaluate the effect of group and time: (Table 5.12). Group allocation was found to have had a statistically significant effect on the Total Score in The HAD at week 7: F (26,51)=1.84, P=0.03. Eta for Group Allocation was 0.12, which is only a small effect. Post hoc analysis of the week 7 results report all 3 groups to be a homogenous set in Total Score (P=0.08). Group allocation did not have any effect on the week 7 results in the subscales anxiety or depression. Both subscales, anxiety (P <0.01) and, depression (P<0.01) reported a statistically significant improvement at week 7. There was no interaction between subscales and group allocation for this effect:(Table 5.11). Eta for both anxiety (0.69) and

depression (0.65), according to Cohen's (1988) guidelines are of a large effect size. Post hoc tests reported both subscales to consist of homogenous subsets at week seven.

Table 5.12: Two way ANOVA for The HAD by allocated group

Dependent Variable: Week 7 outcomes	*df*	*MS*	*F*	η^2	**Post Hoc** Games-Howell
∑ Score					
Group Allocation	2	37.16	3.49*	.12	None
The HAD total score	24	87.98	8.28	.79	
Group allocation * The HAD total score	26	19.54	1.84*	.48	None
Error	51	10.63			
Subscale Anxiety					
Group Allocation	2	8.31	1.15	.03	
Anxiety	16	65.80	9.08**	.69	None
Group allocation * Anxiety subscale	20	7.39	1.02	.24	
Error	65	7.25			
Subscale Depression					
Group Allocation	2	3.85	.89	.02	
Depression	14	36.51	8.47**	.65	None
Group allocation * Depression subscale	14	5.34	1.24	.19	
Error	73	4.31			

Note: * $p<0.05$ ** $p<0.001$

The MCID in the HAD has been reported as a reduction in score in a subscale by two points (Zigmond & Snaith, 1983). The MCID was not achieved on any subscale by the control or experimental groups by week 7: Table 5.11.

On a case-by-case basis, 4 (36%) of the 11 participants in the CDSMP group who had recorded a baseline clinical level of anxiety had achieved the MCID in this measure at week seven. In the PRP group, 14 (54%) of the 26 participants who recorded a baseline clinical level of anxiety achieved the

MCID at week seven. Furthermore, one (25%) of the 4 participants in the control group who had recorded a clinical level of anxiety achieved the MCID at week 7. In the CDSMP group, seven participants recorded a baseline level of clinical depression, five (71%) of who achieved the MCID in this measure at week seven. In the PRP group, 6 of the 11 (55%) participants who had recorded a clinical level of depression at baseline had achieved the MCID. One of the four (25%) Control participants recorded a reduction in score in this subscale by two points.

In summary, the group mean differences were unchanged by participation in either experimental group. At week seven, the experimental and control groups were a homogenous set. There were individual instances where the MCID has been achieved in the subscales of The HAD but these were insufficient in number to reach a group mean significance.

5.2.3 HRQoL

Health Related Quality of Life (HRQoL) was measured with both a disease specific measure; the St George Respiratory Questionnaire (SGRQ) and a general measure – the Assessment of Quality of Life (AQoL).

5.2.3.1 HRQoL: St George Respiratory Questionnaire.

The SGRQ calculates good health to a score of 0 and worse health state to 100. The baseline scores by group allocation were normally distributed: the CDSMP group (skewness = -0.59), the PRP group (skewness = -0.48) and the control group (skewness= 0.297). A one-way ANOVA indicated that there were no statistically significant differences between groups: (Appendix 16).
Paired sample t – tests were performed to evaluate the within group change over time: (Table 5.13). The reported MCID in this outcome measure was a reduction in score by 4 points (Jones et al., 1992). Both experimental groups recorded the MCID and a statistically significant improvement in this measure: (Table 5.13).

Table 5.13: The SGRQ group mean summary results

Allocation	**Baseline Σ Score** *M (SD)* **Range**	**Week 7 Σ Score** *M (SD)* **Range**	**t**	Value **P**	***n***
CDSMP	54.95 (14.38) 23-77	49.63(16.83) 21-76	2.69	0.01	*26*
PRP	50.17 (15.09) 8-74	45.20(15.45) 9-75	3.53	0.001	*56*
CONTROL	50.48 (18.63) 15-83	48.44(22.53) 23-85	.34	0.74	*22*

A two way ANOVA between time and group was computed: Table 5.14

Table 5.14: Summary of two way ANOVA for the SGRQ

Dependent variable: week 7 outcomes	*df*	*MS*	*F*	η^2	**Post Hoc** Scheffé
∑ Score					
Group Allocation	1	24.67	0.09	0.01	
SGRQ total score	89	298.28	1.12		
Group allocation * SGRQ ∑ score	4	244.66	0.92		
Error	8	266.52			
Subscale Symptoms					
Group Allocation	1	1008.01	4.58	0.43	
SGRQ symptoms score	95	538.34	2.45		
Group allocation * SGRQ symptoms	0				
Error	6	220.21			
Subscale Activities					
Group Allocation	2	70.65	0.38	0.02	
SGRQ activities score	57	662.09	3.6**		P=0.97
Group allocation * SGRQ activities	10	144.60	0.79		
Error	35	181.23			
Subscale Impacts					
Group Allocation	1	789.61	2.02	0.24	
SGRQ impacts score	93	329.42	0.84		
Group allocation * SGRQ impacts score	1	70.56	0.18		
Error	7	391.84			

Note: ** p<0.001

5.2.3.2 HRQoL: The Assessment of Quality of Life.

The baseline AQoL Total score for the CDSMP (skewness=0.923), the PRP (skewness=0.658) and the Control group (skewness= -0.86) were normally distributed. A one-way ANOVA reported no significant differences between the experimental and control groups at baseline in total score or in each subscale. The group mean results have been summarised: (Appendix 17).
A two way ANOVA was undertaken to evaluate the effect of group and time. There were no statistically significant differences between the three groups in the four subscales at week seven, all groups had improved: (Appendix 18). Paired sample t–tests reported that there was no significant within group change over the seven weeks, these results have been summarized: (Appendix 19).

5.2.4 Self Efficacy

The minimum and maximum scores possible on this outcome measure range from 12 to 60. The GSES-12 results were normally distributed. Independent sample t-tests revealed no significant baseline differences between groups: Table 5.15.

Table 5.15 Summary data for the GSES-12.

		n	**CDSMP** M (SD)	**n**	**PRP** M (SD)	**value** **t**	**P**
Persistence	Baseline	25	18 (4)	52	18 (4)	-.50	0.69
	Week 7	25	15 (3)	52	14 (3)		
Initiative	Baseline	25	11 (2)	52	11 (2)	-.93	0.45
	Week 7	25	11 (3)	52	12 (2)		
Effort	Baseline	25	13 (3)	52	15 (3)	-1.53	0.21
	Week 7	25	18 (5)	52	20 (3)		
∑ Score	Baseline	25	42 (8)	52	43 (9)	-1.09	0.38
	Week 7	25	45 (7)	52	46 (7)		

A two way ANOVA was undertaken to evaluate the effect of group membership and time:(Table 5.16). There was a significant difference in GSES Total Score at week 7: F (30,32)=2.63, P=0.004. Both experimental groups improved by three units (7%) in Total Score.

In summary, the GSES-12 revealed at week seven statistically significant and comparable improvements between the experimental groups in self-efficacy. There is no established MCID for this outcome measure. An increase to the order of seven per cent in comparable domains such as HRQoL, is considered to articulate with a minimal clinical improvement (Osborne 2003). The control group did not complete this outcome measure, which is a limitation on this finding.

By week seven these results had identified that there was no statistically differences between groups in functional status and mood status. However, the intervention groups unlike the control group recorded a statistically significant and clinically important difference in HRQoL and self-efficacy. The null hypothesis was therefore rejected.

Table 5.16: Two way ANOVA for The GSES-12

Dependent Variable: Week 7 outcomes	*df*	*MS*	*F*	η^2
∑ Score				
Group Allocation	1	31.57	1.15	.04
GSES baseline ∑ score	30	72.13	2.63**	.71
Group allocation * GSES ∑ score	12	45.82	1.67	.39
Error	32		27.41	
Subscale Persistence				
Group Allocation	1	4.07	.5	.01
Persistence baseline	16	16.01	1.9*	.39
Group allocation * Persistence	9	6.17	.76	.12
Error	49	8.13		
Subscale Initiative				
Group Allocation	1	2.34	.46	.01
Initiative baseline	9	6.58	1.29	.17
Group allocation * Initiative	7	7.89	1.56	.16
Error	59	5.07		
Subscale Effort				
Group Allocation	1	9.08	.65	.01
Effort baseline	12	17.55	1.26	.22
Group allocation * Effort	9	9.10	.66	.09
Error	51	13.89		

Note: *p<0.05 **p<0.01

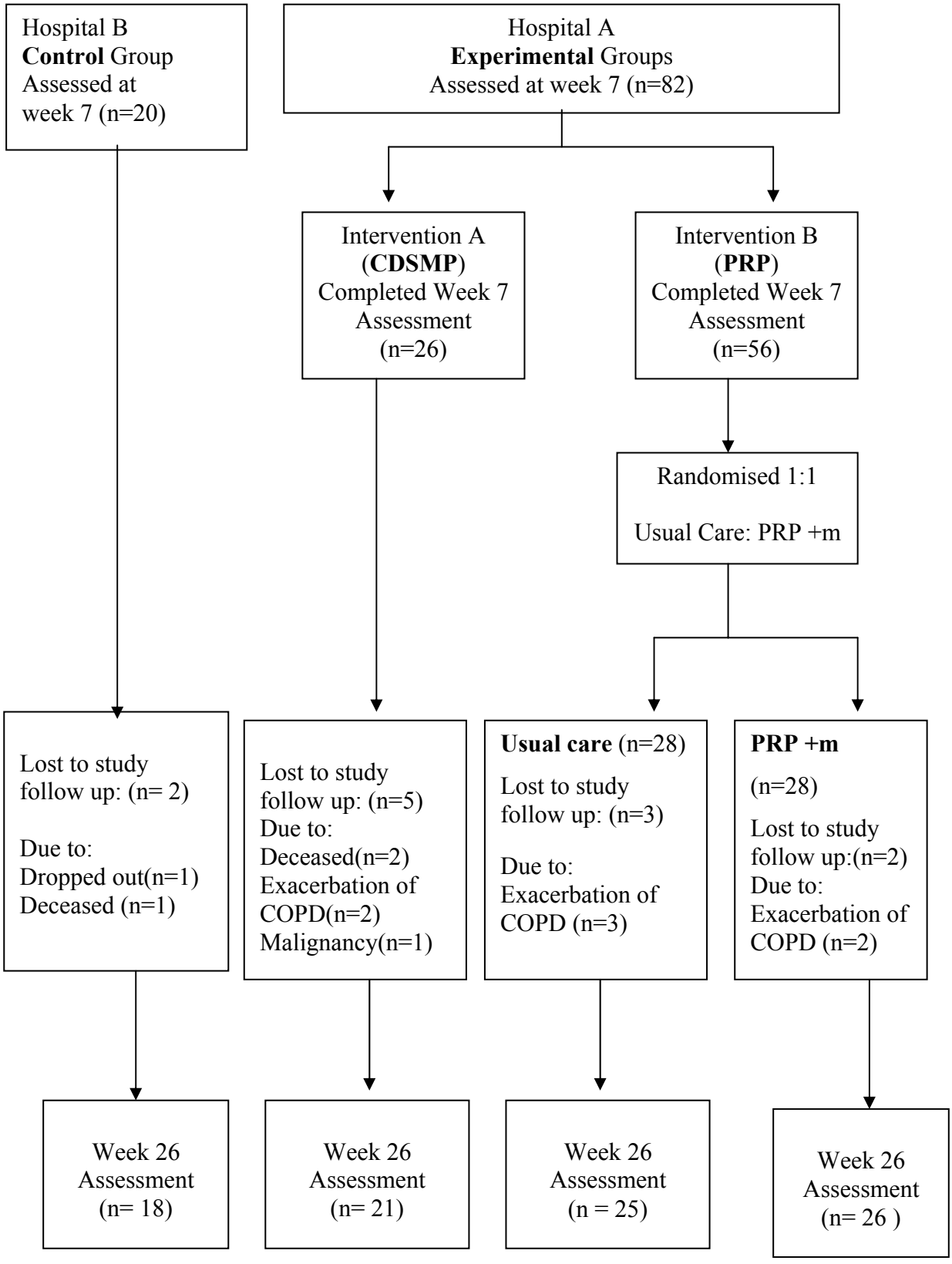
The next section tables the results from the longitudinal evaluation.

5.3 Long term follow up

Participants randomised to the PRP intervention (Intervention B) at baseline were re-randomised following their week seven assessment to either continue to incorporate exercise into their daily life (usual care) or, a structured weekly pulmonary rehabilitation class (PRP+m i.e. Intervention C) until week 26. Participants previously randomised at the commencement of the study to the CDSMP intervention (Intervention A) were encouraged to continue with weekly action plans/goal setting. A flow chart was constructed that summarised all those who participated in the week seven assessment, and all participants were reassessed at week 26: (Figure 5.2).

5.3.1 Randomisation to maintenance PRP

There were 56 PRP participants who completed their week 7 assessment, using methods cited in Chapter Four. These participants were re-randomised to usual care or a weekly structured exercise 'maintenance' program (PRP + m) conducted at Hospital A until their week 26 assessment. There were 28 PRP subjects randomised to usual care and, 28 randomised to PRP+m until week 26. Nineteen (67%) participants agreed to attend the maintenance intervention (PRP+m). Non PRP+m attendees volunteered to continue to attend their week 26 & 52 assessments as scheduled. Reasons volunteered by all those who declined to attend PRP+m were documented, the personal cost (effort) required to exercise was the most common reason cited: (Appendix 20).



Note: exacerbation of: exacerbation of

<u>Figure 5.2:</u> Follow up from weeks 7 to 26 of the study's participants.

5.3.2. The assessment of clinical profiles between PRP interventions

A comparison was made between the clinical profiles of all PRP participants who had completed their week seven assessment. Participants were randomised by sealed envelopes to maintenance PRP (PRP+m) or usual care, and not, by any characteristics. This sub analysis was undertaken to ascertain any between group differences that would need to be accounted for in the interpretation of results at week 26. This analysis was tabled as categorical (Table 5.17) and continuous (Table 5.18) data. No statistically significant differences were found.

Table 5.17 Clinical characteristics at week 7 in the PRP groups-i

	PRP N=28	**PRP+m** N=28	χ^2 statistic	**P** value
Subjects (male)	16	11	1.79	0.18
Australian born	16	20	1.24	0.27
COPD Severity [A]			1.89	0.59
Mild	0	1		
Moderate 2A	8	14		
Moderate 2B	11	6		
Severe	9	7		
Long Term Oxygen Therapy ($LT0_2$)	11	4	1.08	0.59
Never Smoked	2	4	0.75	0.39
Current Smokers	0	1	-	-
Former Smokers	26	23	1.47	0.23

Note: GOLD classification[A]

Table 5.18 The clinical characteristics at week 7 in the PRP groups-ii

	PRP	**PRP +m**	**value**	
	Mean (SD	Mean (SD	**t**	**P**
$LT0_2$ Hours per day	1.8 (1.2	1.6 (1.1	-.39	0.69
$LT0_2$ Litres *(l)* per minute	0.5(1	0.3(0.8	.95	0.35
FEV_1 *l* Actual	1.1(.6	0.9(0.4	1.06	0.29
FEV_1 $l_{\%\ Predicted}$	43(21	40 (15	.67	0.51
FVC *l* Actual	2.4(.9	2.1(.6	1.46	0.15
FVC $l_{\%\ Predicted}$	77(21	71(10	1.53	0.13
TLCO Actual	9.9(4.9	9.6(5.2	.28	0.78
Smoking *Pack Years*	45(25	37(28	1.17	0.25
Age (years)	69(10	67(11	.95	0.35
Co-Morbid Conditions	1.8(1.2	1.6(1.1	.79	0.44
B M I (kg/m^2)	27(6	28(6	-.43	0.67

5.3.3. Week 26 Follow up

Figure 5.3 illustrates the follow up and attrition at week 26 and 52. The next section includes the week 26 group mean results within the week 52 graphs. Raw data for the week 26 assessments is available from the candidate upon request.

5.3.4 Week 52 follow up

In this section where possible, the baseline to twelve-month follow up have been depicted as graphs with the table of results in the appendices. The graphs unless stated otherwise report the mean (M) and 95% Confidence Interval (CI) as the standard deviation (SD) represents just 68% of the variance. A flow chart was constructed to summarise the follow up of participants from baseline to week 52: (Figure 5.3).

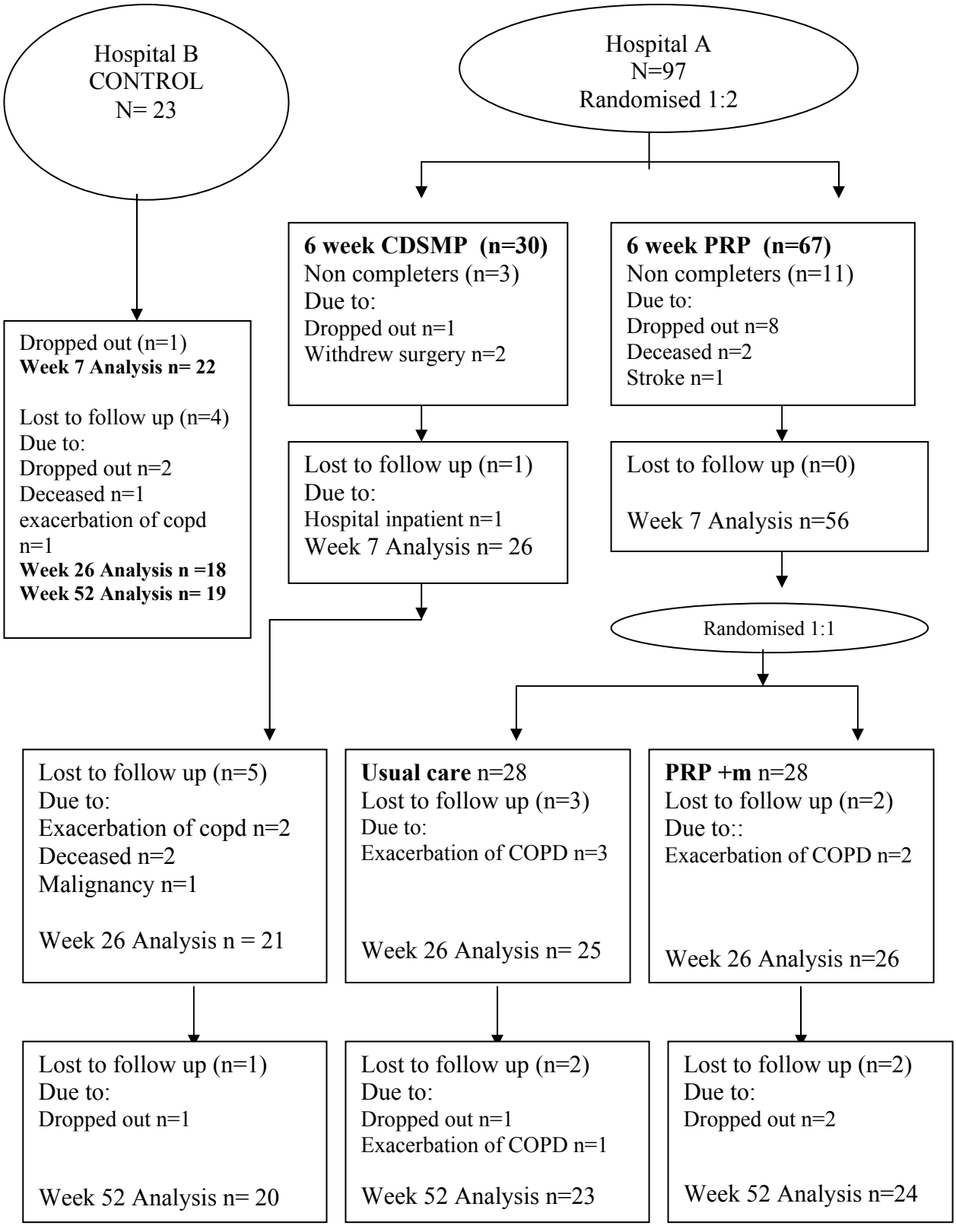


Figure 5.3: Flow chart of study participants until week 52.

5.3.4.1 Indicators for disease progression.

5.3.4.1.1 EXACERBATIONS OF COPD

Prospective use of unplanned health care resources for an exacerbation of COPD in all participants from Hospital A was collated. This data was found to be normally distributed. There was no difference between the three intervention groups in ED presentations or hospitalisation for an exacerbation. This data is presented later in this chapter as a part of the costs of care (Table 5.19).

5.3.4.1.2 FUNCTIONAL CAPACITY

The ISWT by time and group were summarised: (Appendix 24). The Week 52 ISWT for the CDSMP (skewness = -.029), PRP (skewness = -.782), PRP +m (skewness = .162) and Control (skewness = .928) were normally distributed.

A mixed ANOVA, with Greenhouse-Geisser correction, were conducted to assess whether there were differences within the four groups over time and between groups. The main effect of time was qualified by a significant interaction between time and group, F (7.79, 202.44) = 5.31, P<0.0001. Group allocation was not significant in this study F (1,78)=1.18,P=0.32, but the outcomes were different by each group over time. Post hoc Scheffé tests revealed no statistically significant differences (P= 0.39) between all groups at week Fifty-two.

All three experimental groups reported an improvement from their baseline functional capacity that was sustained until week 52. The CDSMP maintained a 4% increase, PRP:16%, PRP+m: 31% increase from their baseline measures. The Control group recorded a 41% reduction from their baseline ISWT measure. The effect size for the improvement in the ISWT at week 52 in the CDSMP (d= .1) and PRP (d =.14) were small. However, the effect size for the

PRP+m group (d= .56) was large, according to Cohen's guidelines (1988). Functional capacity over time by group allocation is illustrated: (Figure 5.4).

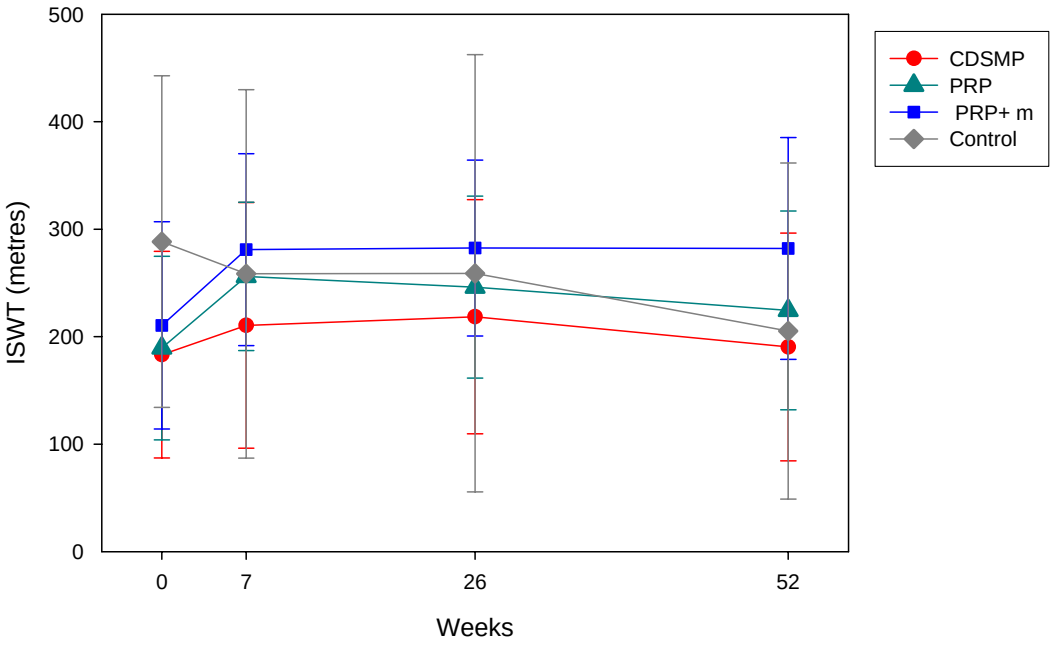


Figure 5.4 The ISWT results by group allocation

A mixed MANOVA was conducted to assess whether there were differences in results by gender and group over repeated measures of time. Significant multivariate effects were found for the main effects of group, F (3,72)=10.3, P <0.001. There was no significant interaction by time and gender, F (3,72)=0.34,P=0.78 or between time, gender and group, F (9,222)=0.54,P=0.84. These outcomes indicate that gender was not a statistically significant determinant in the results.

5.3.4.2 Symptom Control.

5.3.4.2.1 DYSPNOEA.

The MRC Dyspnoea Grade results by allocated group from baseline to week 52 were summarised: (Appendix 21). The Week 52 MRC Dyspnoea Grade for the CDSMP (skewness = -.52), PRP (skewness = .51) and PRP +m (skewness = .63) were normally distributed.

A mixed ANOVA was computed to assess whether there were differences in dyspnoea ratings over time and between allocated group. Results indicated a significant effect over time, F (3,86)=2.92, P= 0.04. A post hoc multiple comparisons test (Scheffé) revealed no statistically significant differences between groups: (Appendix 22). However, the homogenous subsets at week 52 were: PRP and PRP+ m and then, PRP and CDSMP: (Appendix 23). This indicates in this project, the short-term interventions achieved statistically similar outcomes over time. However, the reduction in dyspnoea, over time, was only sustained by the maintenance group (PRP+m). The experimental groups record of dyspnoea over time is illustrated, there was no data recorded by the Control group with this measure beyond baseline: (Figure 5.5).

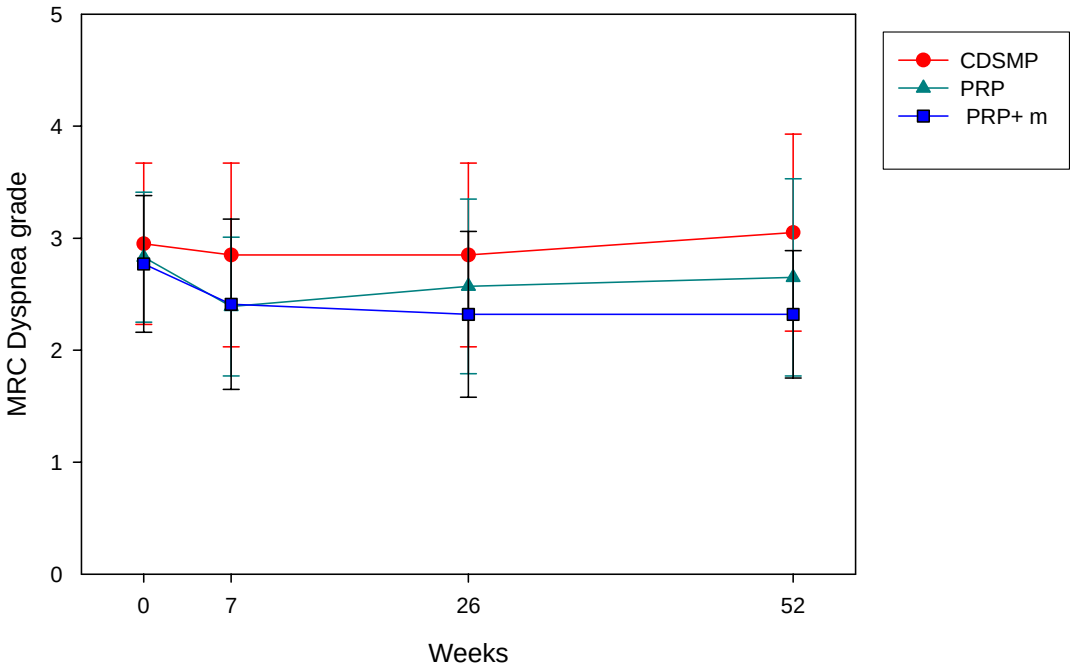


Figure 5.5 Summary data of the MRC Dyspnoea Grade over 12 months

To assess whether there were differences in the Dyspnoea results by gender and allocated group over repeated measures of time and if there was an interaction between gender and group, a multivariate analysis of variance was conducted: (Appendix 25). The interaction was not statistically significant by gender, F (4,56)=0.93, P=0.45 or by gender and group, F (2,70)=0.61,P=0.77. This indicates that gender was not a significant determinant in the report of dyspnoea at week 52.

5.3.4.2 2.MOOD STATUS.

The HAD outcomes at week 52 for the CDSMP (skewness = -.03), PRP (skewness = .32), PRP +m (skewness = -.05) and Control (skewness = 1.09) groups were normally distributed. The results of The HAD by allocated group from baseline to week 52 were summarized. Interestingly, in the Total Score,

in this outcome measure at week 52, the CDSMP and the PRP+m were the only groups to achieve the MCID: (Appendix 24).

A mixed ANOVA, with Greenhouse-Geisser correction, was conducted to assess whether there were differences within the four groups over time and between groups. Results indicated a significant effect over time *F* (2.43, 199.42)=3.59, P=0.02. There was no significant interaction between time and group, *F* (7.29,199.42) =1.29, P=0.26. This indicates that the results over time were independent of group allocation. The effect size for the CDSMP (d=.12) and the PRP group (d=.3) were small and the PRP+ m group (d=.6) was medium. Figure 5.6 illustrates how each group behaved over time.

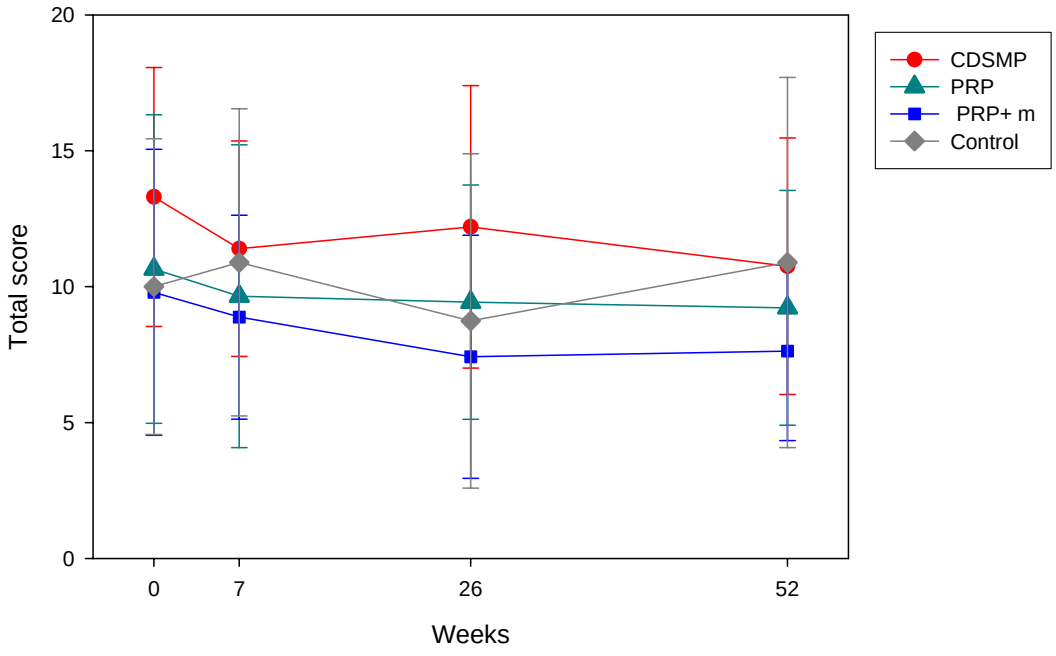


Figure 5.6 Summary results of The HAD Σ Score with 12 month follow up

In The HAD subscale Anxiety there were no statistically significant differences over time, within or between, groups: (Appendix 25). In The HAD subscale Depression, results indicated a significant effect over time,

F (2.47,202.91) = 3.53, P=0.02. There were no significant interaction between time and group *F* (7.42, 202.91)= 1.47, P= 0.18. This indicates that the results over time were independent of group allocation. Figure 5.7 illustrates how each group behaved over time.

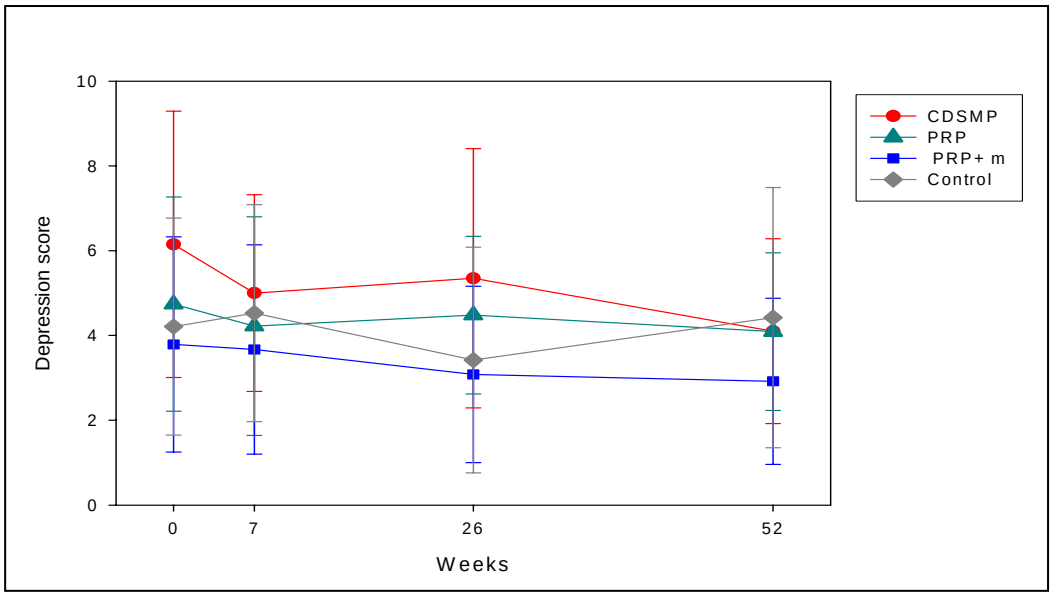


Figure 5.7:12 month follow up of Depression as measured with The HAD

A doubly multivariate analysis was conducted to assess if there was a difference in results over repeated measures of time by group and gender. No statistically significant multivariate effects were found.

In summary, the 12-month follow up in mood status has revealed a statistically significant improvement in Total Score over time by all four groups. However, the CDSMP and PRP+m groups were the only groups to achieve the MCID in this measure. Interestingly, there were no significant changes in anxiety in any group. In the subscale Depression, there was a statistically significant improvement recorded. There was no significant interaction between time and group for this effect. The CDSMP group were the only group to achieve a reduction in the subscale Depression that met the MCID in this measure. Gender was found not to be a determinant of this outcome.

5.3.4.3 Health Related Quality of Life.

The St George Respiratory Questionnaire (SGRQ) outcomes by allocated group from baseline to week 52 were summarised:(Appendix 26). The Week 52 Total Score for the CDSMP (skewness = -.918), PRP (skewness = .103), PRP +m (skewness = .067) and Control (skewness = .507) were normally distributed. Further analysis reports a normal distribution by allocated group in each of this measure's three subscales.

A mixed ANOVA, with Greenhouse-Geisser correction, was conducted to assess whether group allocation over time in the SGRQ Total Score. Results indicated a significant effect over time F (2.48,198.01)=7.21, $p<0.0001$. There were no significant interaction between time and group for this improvement, F (7.43,198.07)=1.01, P= 0.43. At week 52 all groups were a homogenous subset.

The MCID in this measure was sustained at week 52, by the three experimental groups. However, the effect size between experimental groups varied from small for the CDSMP (d=.17) and PRP (d=.41) groups, to medium (d=.61) for the PRP+m group, according to Cohen's (1988) guidelines. The SGRQ total score over time by group allocation is illustrated: (Figure 5.8).

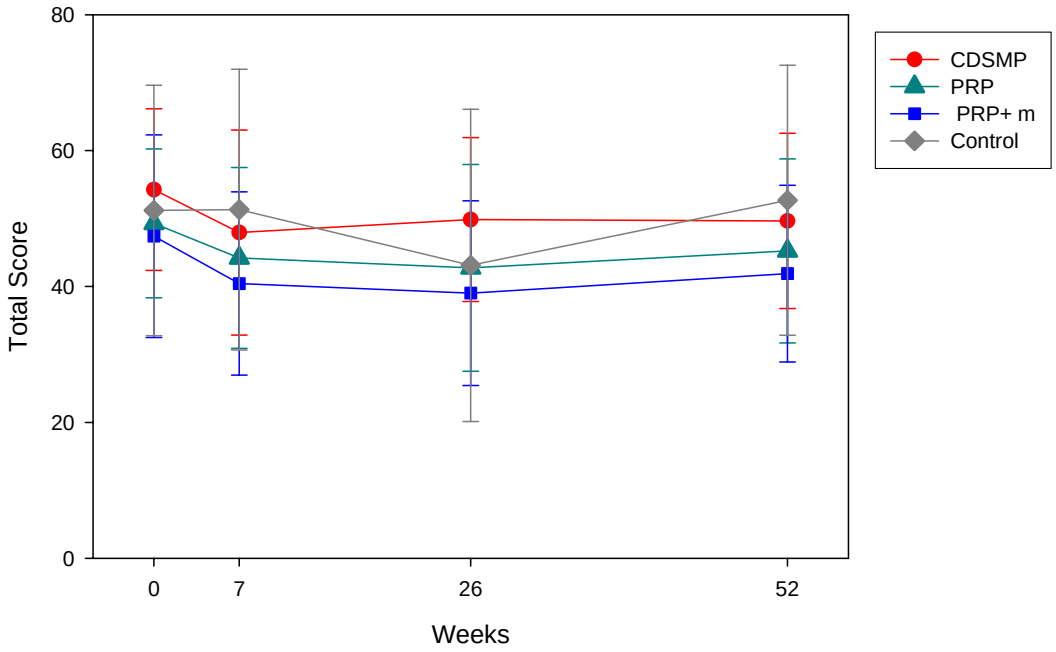


Figure 5.8: Summary results of the SGRQ Σ Score with 12 month follow up

The subscale Symptoms reports those generated by the respiratory condition. There was a significant effect over time F (3,240)=3.03,P=0.03 and group allocation was not significant for this outcome F(9,240)=.92, P=0.51. At week 52, the CDSMP and PRP group mean score indicated a trend back to their baseline levels, the Control group had deteriorated beyond their baseline measure and, in contrast the PRP+m group maintained the MCID in this scale: (Appendix 26).

In the subscale Activities, there were significant improvements in all four groups over time F (3,240)=6.54, P<0.001 and no significant interaction with group F (9,240)=. 55, P=0.83. All four groups reported an improvement in Activity levels sustained at week 52. However, the PRP and PRP+m were the only two groups to maintain the MCID in this measure over the duration: (Appendix 26).

In the subscale Impacts, there were significant improvements over time $F(2.65,211.87)=4.86$, P=0.004 and no effect of group on this outcome $F(7.95,211.87)=1.12$, P=0.35. The experimental groups maintained their improvement over time. The CDSMP group was the only group to sustain the MCID over the duration: (Appendix 26).

A secondary analysis to investigate whether there were any differences in HRQoL by gender and group over repeated measures of time was undertaken using a mixed MANOVA. There was no interaction between time and gender $F(12,65)=.65$,P=0.79 or time, gender and group F(36,845)=.92,P=0.60. Gender was not an influence on results: (Appendix 27).

5.3.4.4 The General Self Efficacy Scale

The Week 52 GSES outcomes for the CDSMP (skewness = .341), PRP (skewness = .946) and, PRP +m (skewness = -.838) and were normally distributed. The group mean results over time were summarized: (Appendix 28).

A mixed ANOVA was conducted to assess whether there were differences within the three experimental groups over time and between groups. Results indicated a significant effect over time, F (3,171)=4.69, P = 0.004. There was no significant interaction between time and group, F (6,171) = .73, P=0.63 for the improved outcomes; all groups improved.

The subscale Effort was the only scale where the improvement from baseline was sustained by all three experimental groups, F (2.49,144.42)=57.75, P<0.001. In the subscales Initiative and Persistence all groups had by week 52 returned to their baseline level: (Appendix 28). The general self -efficacy outcomes over time by experimental grouping Total Score are illustrated: (Figure 5.9).

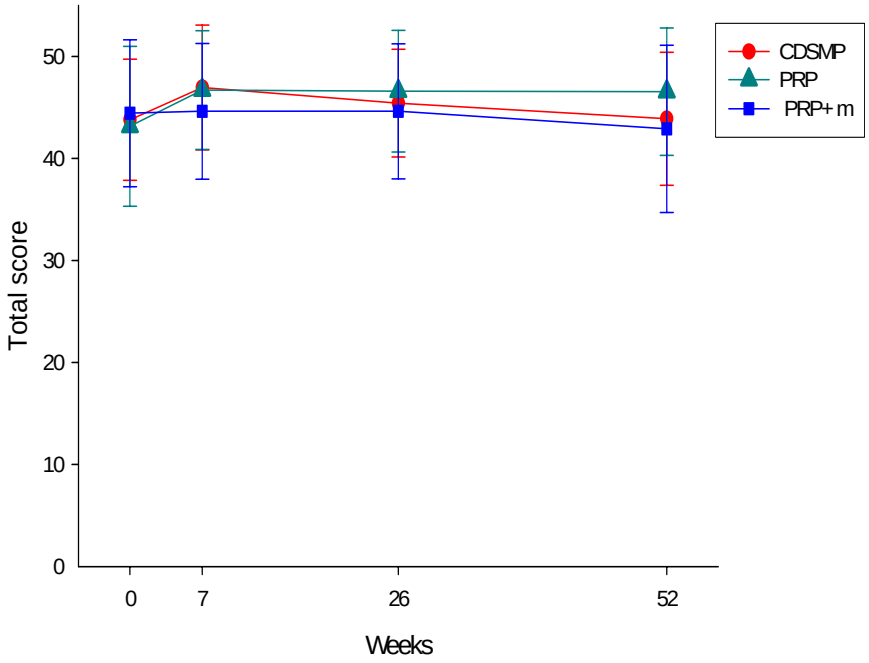


Figure 5.9: The GSES Σ Score with 12 month follow up

A secondary analysis to investigate whether there were any differences in results in each group by gender over repeated measures of time was undertaken using a mixed MANOVA. There were no statistically significant differences between males and females on the dependent variables by gender and group $F(6,112)=.88, P=0.51$. An inspection of the mean and standard deviation scores by gender and group were essentially equivalent.

In summary, by week 52 there was no statistically significant differences between groups or by gender in functional status, HRQoL, symptom control, self-efficacy and unplanned health resource use over the 12 month follow up period in this study. The null hypothesis was therefore accepted.

5.3.5 The summative framework of results

At the start of this project consideration was given to the philosophical underpinning to align these new interventions with. Self-efficacy theory was

the health model selected. When the results at week 52 were amassed however, the following significant relationships were identified: Figure 5.10

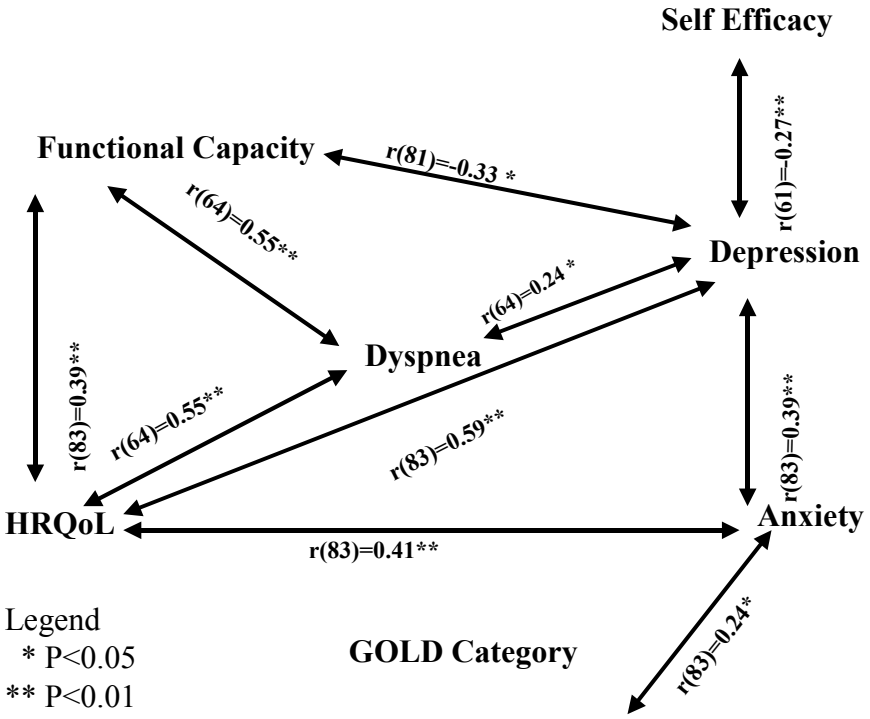


Figure 5.10: The correlations between the study's variables at week 52

There was a significant correlation between self-efficacy and depression. Depression was significantly correlated with a number of the study's dependent variables i.e. functional capacity, dyspnoea and HRQoL.
The next section reports on the costs of care.

5.4 Economic Results

Section 2.4 of the literature review outlined the methods of reporting costs of health care. Improving HRQoL was a core ambition behind this project's interventions. The incremental cost per Quality Adjusted Life Year (QALY) was chosen as the outcome for the cost utility analysis (CUA) of the study.

The QALYs, costs per group and health resource use by group will now be presented.

5.4.1 Quality Adjusted Life Years

At baseline, all groups reported sub-optimal quality of life (Control and CDSMP group utility score = 0.52, PRP group utility score = 0.62). Utility scores were calculated at each assessment time point and, over the twelve months increased to 0.61 (Control and CDSMP group) and 0.72 (PRP+m). The PRP group recorded a deterioration to 0.49. Through out the 12 months follow up period, there were some fluctuations in the utility scores: (Table 5.19).

Table 5.19 AQoL (utility) mean values from baseline to week 52

Time period	Control *Mean (SD)*	CDSMP *Mean (SD)*	PRP *Mean (SD)*	PRP+ m *Mean (SD)*
Baseline	0.52 (.29)	0.52 (.29)	0 .62 (.23)	
Week 7	0.57 (.29)	0.56 (.23)	0.91 (.05)	
% change [1]	**+ 10%**	**+ 8 %**	**+ 47 %**	
Week 26	0.70 (.27)	0.55 (.01)	0.64 (.08)	0.68 (.23)
% change [1]	**+ 35%**	**+ 6 %**	**+ 3%**	**+ 10 %**
Week 52	0.61 (.30)	0.61 (.30)	0.49 (.31)	0.72 (.19)
% change [1]	**+ 17%**	**+ 17%**	**- 21%**	**+ 16%**

Note: [1] % change (improvement) from baseline mean value

5.4.2 Costs

The experimental groups health resource use for the twelve months of the study were totaled and group means calculated:(Table 5.21). and costs totaled: (Table 5.20).

Table 5.20 Costs per intervention group during the study

	CDSMP Σ Costs	PRP Σ Costs	PRP+ m Σ Costs
Hospitalisations: Respiratory	52,229.98	41,514.35	49,969.62
ED Presentations	6,300.00	6,300.00	5,950.00
Outpatient visits: Respiratory	13,328.00	21,760.00	15,232.00
Outpatient visits: other	7,889.00	9,432.50	12,005.00
Intervention costs	5,992.97	75,169.45*	73,357.53
Σ Costs $AUD	**85,808.95**	**154,166.30**	**156,514.15**

Note: * All PRP+m attended PRP prior to maintenance, this figure includes six-weeks PRP for the PRP+m group

The CDSMP, PRP and PRP+m interventions were all new services to Hospital A and the capital costs were included in this analysis as these were actual costs incurred in order to implement the interventions. The mean cost, per participant, was then extrapolated from the available data.

Table 5.21: Health Sector resource use during the 12 month study period

	CDSMP	**PRP**	***PRP + m***	**Value**[1]		
	Mean (SD)	Mean (SD)	Mean (SD)	χ^2	**df**	**P**
Hospital Admissions: Respiratory	1.7 (.8)	1.3 (1.3)	1.5 (1.0)	1.08	2	0.58
Length of stay (days)	14.1 (14.2)	8.9 (8.9)	8.7 (9.6)	.33	2	0.85
Hospital Admissions: Non-respiratory	1.3(.6)	N=1	0	1.89	2	0.39
Length of stay (days)	1.7(.6)			1.5	1	0.22
Ambulatory care visits: Respiratory	2.1 (1.9)	2.9 (1.8)	2.8 (.7)	.97	2	0.62
Ambulatory care visits: Non -respiratory	4.7(5.3)	3.0 (2.9)	4.0 (3.1)	.79	2	0.67
ED presentations: Respiratory	1.0(1.0)	1.0(1.0)	N=1	4.87	2	0.09
ED presentations: Non-respiratory	0	1	0	.00	1	1.0

Note [1]: Kruskal-Wallis Test , N/A: not available

5.4.3 Cost Utility Analysis

QALYs were calculated as the group mean utility score multiplied by the time spent in that health preference state. To generate an incremental cost effectiveness ratio (ICER), the difference in costs and QALYs were calculated using the following equation (as reported in Chapter Two):

$$\text{ICER} = \frac{\text{Costs (intervention group)} - \text{costs (control group)}}{\text{QALYs (intervention group)} - \text{QALYs (control group)}}$$

At the time of writing this thesis the costs of the control group have yet to be communicated by Hospital B. While this study has reported in the literature review that a mere 1% of Australians who should participate in a six-week PRP are able to, it is widely regarded that a six-week PRP needs to be an accessible 'usual care' program. For the purposes of this analysis the six-week PRP became the usual care/control group of the CUA and the added benefits that a maintenance PRP (PRP+m) could generate are evaluated here

as the intervention group. This assumption is consistent with previous reports (Ramsey et al., 2001).

Two methods were utilised to generate a cost utility ratio from the study data. Firstly, this was done directly with the 12 months data from of the study: (Table 5.17-18). Secondly, data was obtained for life expectancy of COPD patients to model costs and consequences beyond the study timeframe.

5.4.3.1 Primary CUA.

The QALYs: (Table 5.17) and costs: (Table5.18) have been reported earlier in this section.

$$\text{ICER} = \frac{(2479.29) - (1121.93)}{(0.72) - (0.49)} = 3156.65$$

Interpretation of the ICER suggests that AUD $3156.65 would be saved for each QALY lost due to the PRP+m intervention.

5.4.3.2. Modelled CUA.

To model the CUA beyond the duration of the study to the lifetime of patients, life expectancy and lifetime costs were calculated. The mortality rate attributable to an exacerbation of COPD was reported in Chapter Two. This report was used to determine the mortality rate observed in patients in the year after discharge from hospital for an exacerbation of COPD (Groenewegen et al., 2003).

An annual mortality rate (MR) for the mean age of each group adjusted for gender differences was determined from Australian life tables (Australian Bureau of Statistics, 2003) for the intervention (PRP+m) and control (PRP) groups. The MR was weighted for the proportion of men and women in each group in this study was calculated: Table 5.22.

Table 5.22 Annual Mortality Rate adjusted for age and gender

	Life expectancy (years)			Annual mortality rate
	Females	**Males**	**Weighted life expectancy**	
PRP group (mean age 69 years)	7.955	8.949	16.9	0.059
PRP+m group (mean age 67 years)	12.26	6.708	18.97	0.052

The calculation of mortality (due to COPD) was modelled on the Groenewegen et al (2003) data set. The 171 patients reported by Groenewegen et al (2003) comprised 39% females and 61% males, with a mean age of 70 years. Weighting the life expectancy by proportion of men and women in the data set produced an (age/sex) life expectancy of 15.95 years using the Australian life tables (Australian Bureau of Statistics, 2003) and an (age/sex) annual mortality rate of 0.062.

The reported MR (Groenewegen et al, 2003) was used to calculate the annual MR and, the secondary calculation of annual MR attributable to COPD was extrapolated from the age/gender calculations of the Groenewegen et al (2003) data set, -a method previously reported (Higgins, 2003; Kuntz & Weinstein, 2001).

In summary;

Reported MR (Groenewegen et al, 2003) = 23% at 12 months
Annual MR $_{TOTAL}$ = -ln (0.23)/1 = 1.47
Annual MR $_{COPD}$ = Annual MR $_{TOTAL}$ – Annual MR $_{AGE/GENDER}$
Annual MR $_{THIS\ STUDY}$= 1.47-0.062=1.41

The modelled life expectancy (and QALYs) for this study was then extrapolated from these equations above. The annual MR attributable to COPD (1.41) was added to the annual mortality rates (age/sex specific) for PRP (0.059) and PRP+m (0.052). The inverse of these summed values (i.e., 1/x) would generate the life expectancy of study patients (Higgins, 2003; Kuntz & Weinstein, 2001). Therefore, the life expectancy multiplied by the utility value generates the QALYs expected for this study's groups: Table 5.23

Table 5.23: Calculation of QALYs expected

	Mortality rate (COPD)	Mortality rate (age/sex)	Total mortality rate	Life expectancy (years)	QALYs expected*
PRP group	1.41	0.059	1.47	0.70	0.34
PRP+m group	1.41	0.052	1.46	0.70	0.50

Note: *The utility scores for PRP, PRP+m at 12 months were 0.49, 0.72 respectively.

The life expectancy was calculated to be 0.70 years across all groups in this thesis project. As the spectrum of study participants was thought to represent patients at various stages of disease, lifetime costs attributable to COPD were based on the 12-month mean resource use of patients in the study. Costs of resource use for the 12 months of the trial were multiplied by the life expectancy for each group Therefore Lifetime costs were calculated for the PRP ((0.70 X 3952.98x39)= $107,916.35) (as the control group), and PRP+m ((0.70 x 5589.79x28)= $109,559.88) (as the intervention group). These results demonstrate that the modelled QALYs generated by the PRP+m group were not terribly more than those generated by a six-week PRP.

A sensitivity analysis is conducted when there is uncertainty in the data collected (Campbell & Torgerson, 1999). A sensitivity analysis was not required as all receipts to calculate costs were retained. A discount rate of 3-5% is usual practice in the calculation of future QALYS. Discounting of QALYs is usually not undertaken until inflation is included in the analysis (Brosnan & Swint, 2001). All costs in this study are reported in 2004 Australian dollars. The cost of inflation in Australia at this interval in time is equivalent to the discount rate (Parliamentary Library, 2004). Therefore, the future QALYs would be equivalent to those reported in Table 5.23.

5.5 Reporting Adverse Events

The CONSORT checklist (Moher et al., 2001) urges the reporting of adverse events or side effects attributable to the interventions. The following outline regarding five study participants was undertaken to account for these occurrences.

One participant who had been randomised to pulmonary rehabilitation on arrival into the gymnasium, day one, week one experienced a conscious collapse whilst commencing her walking program on the treadmill. The participants was taken to Hospital A's Emergency Department and admitted for observation and evaluation. A head Computerised Tomography (CT) scan revealed a stroke three days later. The participant experienced a complete recovery without any deficits but withdrew from the study. The Hospital and University's Ethics committees were notified in writing of the adverse event.

Two participants died prior to completion in the six-week pulmonary rehabilitation intervention. One participant died in her sleep at home without prior indication of deterioration in her clinical state. The participant's family and respiratory physician declined a post mortem citing her severe COPD, age and multiple co-morbidities. The second participant successfully completed the six-week PRP intervention. Her week seven assessment was postponed to allow her the opportunity to enjoy a day of shopping with family members. The participants reported chest pain on exertion at home, contacted the metropolitan ambulance service and was transported to Hospital B. During her assessment in the Emergency Department her chest pain exacerbated and was complicated by the acute onset of pulmonary oedema. Treatment with continuous positive airway pressure was successful but the patient had tired. The participant's family refused permission for the participant to be intubated for assistance with ventilation as the participant had pre-existing limitation in resuscitation orders in place. The participant died in the Emergency Department of Hospital B with her family in attendance. The Emergency Department Physician in charge of the participant's care contacted this candidate at the family's request to inform the candidate that the participant's

involvement in the pulmonary rehabilitation intervention was not a catalyst to her cardiac event.

Two participants reported at week seven side effects from participation in the six-week PRP intervention. Both sedentary insulin dependent diabetic participants had embraced walking into their daily routine and were requiring less insulin each day. No participants from the CDSMP or the PRP+m intervention group recorded an adverse event.

The next chapter discusses an interpretation of these results.

Chapter Six Discussion

This chapter brings together the aims and outcomes of this project. The chapter starts with a synopsis that reiterates the findings of the project. This is then followed by the candidate's interpretation of the results drawing upon the research literature to support the interpretation. Next, the limitations of the study are discussed considering the study's internal and external validity. This is followed by the strengths of the project and conclusion of the chapter.

The study had a number of aims, to explore whether self-management programs offered a genuine alternative as a therapy for people with COPD who may not be able to attend a rehabilitation program. The first aim was to explore the effect of the six-week interventions (Interventions A and B) as compared to usual care on functional status, symptom control, HRQoL and self-efficacy. The second aim was to evaluate the duration of benefits achieved by the six-week interventions and, explore whether a maintenance rehabilitation program (Intervention C) added benefit to participants who had attended a six-week PRP. In addition, it became apparent by the literature search undertaken for this project that the known efficacy of conventional outpatient based COPD therapies had largely been evaluated in men. The prevalence of COPD at Hospital A by gender was almost equivalent. In this setting, reviewing results by gender seemed sensible. The third aim was to undertake a comprehensive analysis of health resource use. This was intended to identify whether unplanned health resource use could be curtailed by participating in these health-promoting interventions. The economic evaluation was undertaken to illustrate that the costs of the interventions could be defended by an improvement in the participant's QALYs.

6.1 Synopsis

Every few years the AIHW publishes statistics which outline the prevalence of COPD in Australia (AIHW, 2002a ; 2005b). The AIHW had reported that

there was a greater prevalence of COPD in men (133/100,000) as compared to women (87/100,000) (AIHW, 2002a). The higher prevalence of COPD in Australian men is consistent with global trends (WHO, 2006). In this project, as reported in Chapter Five approximately half of the study's referrals and, uptake to the project were females. The close to equal ratio of referrals by gender is in contrast to reports that gender had been identified as a barrier to referral (Harlan et al., 1995; Hellman & Williams, 1994). The equal rate of referral by gender in our study was consistent with the equal presentation by gender for an exacerbation of COPD at Hospital A, as outlined in Chapter One. The equivalence of COPD by gender at Hospital A contrasts with the national rate of prevalence by gender and could be attributed to the industrial sector of the metropolitan city the hospital is located in. Factors other than cigarette smoking (especially pollution) were reported in section 2.1 of this thesis as contributors to the development of COPD.

For people with COPD who were randomised to either the six -week CDSMP or PRP, benefits were evident by week seven in functional capacity and HRQoL. The Control group, when re-evaluated following a six-week period of usual care recorded a statistically significant deterioration in functional capacity and no change in their HRQoL scores. This finding suggests that participation in either intervention confers benefit when compared to usual healthcare. The minimal clinically important difference in HRQoL was recorded by both intervention groups at week seven. This outcome infers that neither intervention confers more or less HRQoL than the other. Both six

week intervention groups recorded statistically significant improvements in functional activity and, an equivalent improvement in their self-efficacy scores which are previously unexamined comparisons. Participation in either the six-week CDSMP or PRP did not generate a significant improvement in mood status at week seven when results were compared with a control group. This finding reinforces the value of a control group when evaluating the true effect of an intervention in the clinical setting.

In this study's second experiment, the PRP participants following their week seven assessment were re-randomised to a weekly maintenance program or usual care. No significant differences were found between the PRP and PRP+m groups at baseline. When all of the study participants were re-evaluated at week 26 and week 52, the Control group continued to record reduced functional capacity as compared to their baseline measure. The intervention groups recorded sustained improvements of different magnitudes (d=0.1-0.56) with, the PRP+m group recording the greatest effect size.

There were no significant differences between the three intervention groups for a presentation to the ED or hospital admission with an exacerbation of COPD or for treatment of co-morbid conditions over the 52 weeks of the study. As identified in Chapter Two, functional status and exacerbations of COPD are considered to be the primary indicators of disease progression in COPD. This suggests that the generic six-week CDSMP can delay disease progression in COPD, which had previously not been published. In addition, a PRP+m program does not reduce unplanned need for health resource use or generate a reduction in the report of dyspnoea any more than a six-week PRP or the CDSMP. While participation in an intervention group generated a significant improvement in the report of HRQoL this improvement did not last over the 52 weeks duration. Improvements in mood status were sustained until week 52 by the six-week CDSMP and long term PRP+m group.

The second research aim for this project included an evaluation of whether health outcomes differed by gender. All dependent variables were evaluated and gender was found not to have had a statistically significant effect on these

health outcomes. There is little in the literature to compare this evaluation to. Currently there is an absence of reported randomised COPD studies that have comprehensively evaluated the influence of gender over a multitude of health outcomes.

Self-efficacy had been reported in the literature as a mediating variable on health outcomes in COPD. This study was unable to demonstrate any such relationships. Instead, a reduction in depression was identified to have had a significant correlation with improvement in all of this study's other dependent variables.

Lastly, the costs of care were calculated with the available data. The control data set has yet to be made available for analysis in this project and the Medicare data set for health resource usage was unavailable on all study participants at the time of writing. The costs of care were limited to comparing the intervention and hospital costs of care. The CUA demonstrated that the PRP+m intervention generated more QALYs despite costing more per head to provide. When the CUA results were modelled for lifetime costs and life expectancy the PRP+m intervention did not prove to be too much more expensive than the PRP intervention.

6.2 Synthesis of the Findings

6.2.1. Indicators of disease progression

6.2.1.1. Exacerbations of COPD.

The literature review had reported that there remains ambiguity in the definition of an exacerbation of COPD (Rodriguez-Roisin, 2000). Despite the lack of uniformity in a definition, an exacerbation is well recognised as a significant indicator of disease progression in COPD (Donaldson et al., 2002; Gerald & Bailey, 2002; Wedzicha, 2002; Wilkinson et al., 2004). In this project, all study participants who were admitted to Hospital A or elsewhere alerted the candidate of their hospital admission with an exacerbation of COPD or other complaint. As outlined in the study's consent form their

medical file was reviewed and the reason for their admission recorded. Table 5.21 reported each group's respiratory and non-respiratory inpatient admissions, their length of stay, ambulatory care visits and emergency department presentations. Interestingly, there were no statistically significant differences between all three intervention groups over the 12-month duration of this project in any of these areas. At the time of writing this thesis the Control groups healthcare use remains unaccounted for which limits possible comparisons to usual care. However, the mean presentation rate of two hospitalisations for an exacerbation of COPD per person in this study was consistent with what had been previously reported (Donaldson et al., 2003; Miravitlles et al., 2004). There are currently no published reports that directly compare these three interventions employed in this study in prospective health care use.

In Chapter Two, the candidate had identified that a systematic review of COPD self-management programs had reported that there was no significant difference in hospital admissions in participants when compared to those receiving usual medical care (Monninkhof et al., 2003). In contrast, this study's use of the Stanford Model CDSMP was able to demonstrate that participation in a CDSMP as compared to a short or long term PRP resulted in an equivalent rate of health resource use. This study however, did not record reduced planned physician visits e.g. outpatient's appointments, which is consistent with other reports (Lorig, Sobel et al., 1999; Swerrissen et al., 2006). At the same time, the health resource usage by participants in this project was not excessive and reduced planned physician visits was not ever likely to have been possible.

6.2.1.2. Functional status.

Reduced functional status has been identified as a key feature of disease progression in COPD (O'Shea et al., 2004). In Chapter One, the average age for the onset of COPD in Australia was reported as 60 years for men and 63 years for women (AIHW, 2002b). The average age of the study participants was 68 years, which was not significantly different from Hospital B's cohort.

In the general population, advanced years had been reported as an antecedent to reduced functional status (Franssen et al., 2004) and, refuted as a barrier to improving functional status (Conn et al., 2003). This latter report was a premise upheld by our study.

For ease of discussion, functional status has been divided into the two separate areas of functional capacity and functional performance, as this is how the literature was presented in Chapter Two.

6.2.1.2.1 FUNCTIONAL CAPACITY

The utility of the Incremental Shuttle Walking Test (ISWT) (Singh et al., 1992) was reported in Chapter Two. In the previous chapter, Table 5.5 reported that the two six-week intervention groups were a homogenous group in functional capacity at baseline (P=0.98). Both intervention groups recorded a statistically significant (P<0.01) improvement in functional capacity at week seven (see Table 5.6). Remarkably, the control and two six-week intervention groups were a homogenous set at week 7 (P= 0.47) as, the intervention groups had improved and the control group were worse (see Table 5.6). Therefore, the null hypothesis that there would be no differences between the control and the two intervention groups at week seven was accepted.

This project was sufficiently powered at week 7 to test this hypothesis. The required sample size to test this hypothesis was determined by established methods (Norman & Streiner, 1999). We had calculated the number of participants to provide 80% power to detect a significant difference (P<0.05) in functional capacity with the ISWT pre and post, a six-week intervention (Dyer et al., 2002; Singh et al., 1992). This study's sample size at week seven (n=104) was sufficiently powered to confirm these results.

Improvement in functional capacity following participation in a twice weekly six-week PRP had been identified as an expected outcome (BTS, 2001). The effect of PRP participation on exercise capacity as compared to a control group was reported in Chapter Two (Salman et al., 2003). The Salman et al

(2003) meta analysis calculated a large improvement in functional capacity following PRP participation (d=0.71) and, a 76% reduction in functional capacity in the usual care arm. In this project, the improvement in the PRP arm was of a small effect size (d=0.32) at week seven and also a reduction in functional capacity by the usual care arm (15%) was identified. The magnitude of change in this project is different but the results of this study trend in the same direction as the Salman et al (2003) meta analysis.

An earlier report had detailed that PRP participants when compared to those attending a PRP+m program at week 52 recorded no difference in functional capacity (Vale et al., 1993). The results from this project are in keeping with this earlier report. Functional capacity was reassessed at week 26 and 52 in this project. By the study's end at week 52 all groups as reported in the previous chapter were a homogenous subset (P= 0.39). The CDSMP, PRP and PRP+m maintained a 4%, 16% and 31% increase from their baseline measures respectively. In contrast, the Control group recorded a 41% reduction from their baseline ISWT measure. As reported in Chapter Five, these results were also examined by gender and there was no statistically significant differences identified. This study's null hypotheses that there would be no significant difference between all groups at week 52 or, by time gender and group were therefore accepted.

Multiple regression was performed to help identify a model that best explains increased functional capacity in this study's sample of people with COPD. The collective week 52 ISWT results of the experimental groups were normally distributed (skewness = -0.175) and became the dependent variable of a multiple regression analysis. Hierarchical multiple linear regression identified that the baseline ISWT measurements and the MRC Dyspnoea grade as measured at week 52 significantly predicted increased functional capacity at week 52; F (2,61)=36.70, P<0.001:adjusted R^2 value of 0.53. This indicates that 53% of the variance in the week 52 ISWT results can be determined by this model. Chapter Two summarized the mechanical disadvantages people experienced with COPD, which would explain the influence of dyspnoea on functional capacity. The literature had reported that the perception of

dyspnoea was influenced by physiological, psychological, social and environmental influences (ATS, 1999a). A behavioural intervention is considered to draw upon psychological, social and environmental influences. This project has demonstrated that a self-management program can improve functional capacity in people with COPD which is this project's novel finding.

Functional status is recognised as a predictor of disease progression in COPD. The CDSMP group maintained a statistically significant improvement in functional capacity at week 52 which suggests that disease progression was delayed especially when compared to the control group.

6.2.1.2.2. FUNCTIONAL PERFORMANCE

There were a number of limitations with the use the use of pedometers as a strategy to measure functional performance as reported in Chapter Two and, experienced in this project. It has been recognised that the reliability and mode of mechanism between different brands of pedometers makes comparisons difficult (Schneider et al., 2004). To offset potential bias all participants wore the same brand of pedometer to reduce the variability between and within groups. In addition, stride length was calculated in each participant at baseline to enable distance per day to be recorded, in addition to steps. The inclusion of stride length should have helped to reduce artefact in recordings (Crouter et al., 2003; Tudor-Locke & Myers, 2001). However, because of the inclusion of recording distance walked per day three study participants (one CDSMP, two PRP) did not have pedometers fitted as their stride length was < 30 centimetres (the minimum default on the brand of pedometer used in this study). In addition, pedometers failed to consistently record data with another three slow walking study participants. This was not an unexpected observation with previous reports that pedometers were unable to record distances accurately at a slow walking pace (<0.9 $m.s^{-1}$) (Bassett, 2000; Crouter et al., 2003; Cyarto et al., 2004; Le Masurier & Tudor-Locke, 2003). Additional data was unusable as the result of human error. A number

of pedometers remained clipped to clothing and did not survive the rigors of a washing machine. An equal number were reported to have fallen into toilets or, of more concern, broke, when the wearer fell during a routine walk on the roadways. Participants also confessed they forgot to wear their pedometer for days at a time. These inadvertent errors resulted in approximately half of the pedometer data available for evaluation: (Table 5.7). Interestingly, there were no significant differences between the PRP and CDSMP group in steps per day (P = 0.15) or distance walked (P = 0.17) over the six-week intervention. Therefore this project's null hypothesis that there would be no differences between groups at week seven is accepted.

The PRP group covered more distance with fewer steps than the CDSMP group (1914 steps/kilometre vs. 2073 steps/kilometre). Height, BMI and age are known to influence walking ability (Carter et al., 2003; Enright et al., 2003; Troosters et al., 1999). Table 5.3 in the previous chapter had reported that there were no baseline differences between the two groups in any of these variables. Improved cadence in the PRP group is consistent with one of the goals of a PRP as described by the ATS: "better pacing enables patients to walk further with less breathlessness" (Society, 1999b ,P.1666). Conversely, the PRP group whilst clearly more efficient in their stride did not walk further than the CDSMP group.

There is speculation in the literature as to whether an increase in functional capacity generates an increase in functional performance for people with COPD who participate in an intervention such as a PRP (Garcia-Aymerich et al., 2004). To investigate if there was a significant association between each participant's steps per week walked and, change scores in the ISWT between week seven and baseline, a correlation was computed using all cases that had a full six-week data set. The Spearman rho statistic was calculated, (r_s (33) = 0.19, P = 0.26) which identified no statistically significant relationship between functional activity and disease severity as classified by GOLD (r_s (32) = 0.19, P = 0.29). These results support the notion that functional ambulatory activity is predicted by other factors and not disease severity or participation in

a particular type of intervention (Sin et al., 2004; Trost, Owen et al., 2002). There was, however, a negative correlation between week seven MRC dyspnoea grade and steps walked (r_s (32)= -0.52, P=0.002). Using Cohen's (1988) guidelines, the effect size is larger than typical.

The literature review had reported that the normative value for steps per day in the chronically unwell was unknown (Tudor-Locke & Myers, 2001). To appreciate where this project's results sit when compared to other reports is therefore uncertain. A recent meta-analysis identified the lack of reports on the effects of interventions on walking in large cohorts of people (Ogilivie et al., 2007). Instead, international and national guidelines recommend individuals undertake at least 30 minutes of moderate functional activity on most days of the week (ACSM, 2000b; NHF, 2001; Pate et al., 1995). There has been speculation that 5500 steps per day should articulate to 30 minutes a day in sedentary or older people (Jordan et al., 2005; Tudor-Locke & Myers, 2001). In this project, the median value for steps per day was far greater than these reports with the CDSMP recording *M* 21,357 steps per day and the PRP *M* 12,632 steps per day. Participation in physical activity has been reported to be mediated by social support and role modelling (Dishman et al., 1985). To date no CDSMP has reported the use of pedometers as an adjunct to program evaluation. However, an increase in functional activity in CDSMP graduates had been reported (Holman et al., 1989; Lorig, Chastain, Ung, Shoor, & Holman, 1989; Lorig et al., 1993) but limited by the lack of standardized methods in data collection.

Pedometers were worn by this project's participants for the duration of the six-week interventions. Where a full six-week data set was recorded, a Friedman test was conducted to identify if there were differences among the mean ranks of the six-weeks, χ^2_5 = 44.04,P=0.001. Three orthogonal contrasts were performed using Wilcoxon tests with Bonferroni correction (comparison wise alpha = 0.017). The contrasts (n=34) between week one and two and week five and six were significant but not week three and four. Participants walked

further in week two than week one and, in week six than week 5. This suggests that overall, participants did not increase their functional activity progressively each week despite both intervention groups recording a significant improvement in functional capacity.

The data were also examined to identify if there were differences by gender in functional activity. The analysis revealed that there were differences within the mean ranks of the six-weeks with both female $\chi^2_5=30.79, P<0.001$ and male participants $\chi^2_5=28.11, P<0.001$. The mean ranks revealed that female participants (n=20) tended to progressively increase the number of steps walked each week: (Appendix 29). Three orthogonal contrasts were performed using Wilcoxon tests with Bonferroni correction (comparison wise alpha = 0.017) within each sample examined by gender. There were no statistically significant differences in pedometer recordings between each progressive pair of weeks in male participants (n=25). Female participants recorded a statistically significant difference between week one and two only. This suggests that there was no statistically significant difference in functional activity over the six-weeks of the intervention by gender. Therefore, the null hypothesis that there would be no significant difference between groups by gender is accepted.

6.3 Symptom Control

6.3.1 Dyspnoea

Dyspnoea had been reported as the cardinal symptom of respiratory disability (Abramson et al., 1996; Nici et al., 2006). The MRC dyspnoea scale had been considered to be less sensitive to rapid interventions (Society, 1999a). In this instance, a statistically significant difference and, a large effect size had been reported by the PRP group which is consistent with other reports (Ando et al., 2003; de Torres et al., 2002). The significant effect of PRP participation in reducing dyspnoea had also been reported in a number of randomised controlled trials with other instruments and follow-up of various durations (Goldstein et al., 1994; Hui & Hewitt, 2003; Reardon et al., 1994; Ries, Kaplan, Robert et al., 1995; Simpson et al., 1992; Strijbos et al., 1996; Wijkstra et al., 1994). Pre and immediately post participation in the CDSMP program, there was no statistically significant difference (P= 0.68) or, clinically important difference, in the report of dyspnoea as measured with the MRC Dyspnoea scale. There have been no reports to date of the Stanford model CDSMP program utilizing the MRC Dyspnoea Scale as an outcome measure with which to compare this finding. However, it had been reported that increased symptom control was achieved by CDSMP graduates (Lorig, Sobel et al., 1999). The utility of disease specific HRQoL questionnaires to evaluate dyspnoea in cross sectional studies had been previously reported in the literature (Hajiro et al., 1998a). The SGRQ reports the impact of dyspnoea as they relate to functional situations (Meek & Lareau, 2003). Furthermore, the CDSMP group recorded significant and clinically important improvements on the SGRQ which suggests that when measured with other questionnaires increased symptom control was achieved in this project by the CDSMP group as well.

The MCID was not achieved by either six-week intervention group as measured with the MRC Dyspnoea scale. This outcome could be explained by mitigating factors that influence the perception of dyspnoea. As discussed in Chapter Two, the duration the symptom has been experienced by the patient (Boezen et al., 1998), cerebral processes (Jones, 2000), age, social, and environmental factors (ATS, 1999a) influence the perception of dyspnoea.

None of these mitigating influences were likely to have changed during a six-week intervention.

Participants reporting about a symptom they had lived with over many years may not perceive any improvement in the perception of dyspnoea in a brief period of time. The chronicity of a symptom provides a case for a repeated measures design (Meek & Lareau, 2003). When re-evaluated at week 26, the CDSMP, PRP and PRP+m groups reported a group mean decrease in the report of dyspnoea of 5%, 11% and 18% respectively. However, these group mean reductions were not statistically significant when compared against their baseline group mean scores. This meant that all three experimental groups were a homogenous subset by week 26 (P=0.36). This outcome is in contrast to one published study where a short term PRP reported a significant result as measured with the MRC Dyspnoea scale, that was sustained until 24 months (P=0.001) (Guell et al., 2000). While it is possible that a six-week PRP can confer a sustained improvement in the report of dyspnoea beyond the duration of the intervention, this project was unable to demonstrate this.

In the longer-term evaluation, it was found that by week 52 both the PRP and PRP +m and, the CDSMP and PRP groups were homogenous subsets. The CDSMP did not report a statistically significant reduction in dyspnoea at any point in time over the study period. However, this group had maintained their baseline status and had not deteriorated. A within group paired Student's t test reported that the PRP +m group were the only group to have maintained a statistically significant reduction in dyspnoea from baseline when compared with week 52 (P=0.02). Exercise induced dyspnoea in a controlled environment with supportive staff in attendance was cited as a mechanism that desensitises the individual to the perception of dyspnoea (Carrieri-Kohlman et al., 2001; Reardon et al., 1994). Interestingly, the PRP +m group did not maintain a statistically significant improvement at week 26 (P=0.06) yet reported improved dyspnoea status at week 52. This suggests either an anomaly or, the variability in symptoms that may be experienced over the duration with a chronic health condition. Further analysis revealed that there was no interaction by gender or gender and group in the final results at week

52. There are no reports of studies between PRP and CDSMPs or, PRPs with PRP+m over a 12 month period to compare these results to. These results strongly suggest that continuing in a weekly rehabilitation program is an effective means of maintaining a reduction in the perception of dyspnoea, as the effect of short term programs is not sustained until 12 months.

6.3.2 Mood status

Anxiety and depression had been identified in Chapter Two as affective symptoms (Anderson & Burckhardt, 1999). The baseline dual occurrence of these symptoms in the study cohort as reported in Chapter Five, was consistent with the literature (Kunik et al., 2005). The baseline prevalence of anxiety (40%) was comparable to earlier reports (Dowson et al., 2001) . The baseline prevalence of depression (20%) was also consistent with reports in the literature (Norwood, 2006; van Ede et al., 1999). However, the prevalence of these symptoms in the local setting has been largely unreported and has usually been extrapolated from international reports.

The control and both intervention groups recorded a significant reduction in affective symptoms at week seven. Previous reports as described above, had identified that the CDSMP participation confers a significant reduction in anxiety and depression (Barlow et al., 2000; Lorig, Sobel et al., 2001) and similarly with participation in a PRP (ATS, 1999b; Paz-Diaz, Montes de Oca, Lopez, & Celli, 2007). Although other randomised controlled COPD studies had reported no statistically significant reduction in depression (Ries, Kaplan, Robert et al., 1995) or anxiety (White, Rudkin, Harrison, Day, & Harvey, 2002) following PRP participation. In this study, the inclusion of a control group enabled the true effect of interventions on health outcomes to be evaluated. There were individual instances where the MCID has been achieved in the subscale's of The HAD at week seven in all three groups but these were insufficient in number to reach a group mean significance. However, these results changed over time.

By week fifty-two, no group had recorded an improvement in anxiety over time or by group F (3,82)=1.22, P=0.31 in contrast to the results recorded in the subscale for depression; F (2.43,199.42)=3.59, P=0.02. The CDSMP and the PRP+m groups additionally achieved the MCID in the total score on the HAD by week 52. Interestingly, by week 52, the CDSMP group also achieved the MCID in the Depression subscale. Depression had been identified as associated with low self efficacy (Bandura, 1982). The CDSMP group achieved a significant improvement in mood status and self-efficacy in this project. In the previous chapter, a moderate correlation (r = -0.27) between self-efficacy and depression was reported: (Figure 5.10). Based on the results generated by this project, a reduction in depression facilitated improvements in other health outcomes as well.

The improvement in affective symptoms is not unexpected but occurred well after completion in this project's interventions. This may be due to either an improvement in affective symptoms, arises secondary to improvements in the other health outcomes. Alternatively it has been reported that a response shift (Sprangers & Schwartz, 1999) can occur in longitudinal evaluations when self report measures are used. Chapter Two had identified that reduced mobility and social isolation were amongst a number of triggers recognised to induce depression in people with COPD (Light et al., 1985; Ninot et al., 2002; Toshima et al., 1992). In addition, depression was reported as a factor that may influence HRQoL outcomes in COPD (Kim et al., 2000). The process of participating in the interventions and/or the assessments could be considered a means of reducing social isolation and would explain the improvements recorded in some instances by the control group. The previous chapter had reported an improvement in HRQoL and functional capacity results across all intervention groups. Figure 5.10 depicted the significant correlation a reduction in depression had with the other variables this project had examined. It is probable that the clinically important difference achieved in the Total Score and Depression subscale followed on due to the improvements in the other variables this project evaluated. The influence of gender was also evaluated and found not to be a determinant on mood status. This latter result is useful as little is known as to whether gender is an influence on

responsiveness to an intervention or, on the report of affective symptoms in people with COPD.

6.4 HRQoL

The Assessment of Quality of Life (The AQoL) was the generic HRQoL outcome measure used in this study for the dual purpose of a cost utility analysis and as a generic HRQoL measure. The AQoL demonstrated no difference by time or groups, which contrasts with the results reported with the disease specific HRQoL measure. The AQoL had been validated as a generic tool in studies in the Australian population (Hawthorne et al., 1999), in the outpatient setting and for use with chronic health conditions (Hawthorne, Cheok et al., 2003; Hawthorne, Osborne et al., 2003). Previous reports have indicated that a generic tool may not always show improvement following PRP participation (Ries, Kaplan, Robert et al., 1995) which was this study's experience. It has also been reported that generic HRQoL measures are more prone to a response shift than discrete HRQoL questionnaires in clinical studies (Wilson, 1999). This project's results using a generic HRQoL questionnaire were quite different.

The disease specific measure, the St George Respiratory Questionnaire (SGRQ) demonstrated that participation in either intervention group conferred a statistically significant improvement in HRQoL and, the group mean change articulated with the MCID of this measure:(Table 5.13). A statistically significant improvement in HRQoL following participation in a PRP (Lacasse, Brosseau et al., 2003b; Persson, Olseni, & Lagerstedt, 2000; Rossi et al., 2005) and the Stanford model CDSMP (Lorig, Sobel et al., 2001) is consistent with previous reports. The change in the Control group was not significant (P=0.74) at week seven.

In this experiment, the results demonstrate that participation in either a PRP or the generic Stanford model CDSMP may confer equivalent statistical and clinically important improvements in HRQoL. The required sample size to test this study hypothesis was determined by established methods (Norman & Streiner, 1999). We had calculated that a minimum of 63 study subjects would provide 80% power to detect a significant variance ($P<0.05$) in HRQoL as measured with the SGRQ following participation in a six week rehabilitation program (Schunemann et al., 2002). The study's sample size at week seven (n= 104) was sufficiently powered to confirm these results. To date, there is an absence of COPD studies that have reported a generic and disease specific interventions when compared in a randomised study conferred an equivalent MCID in HRQoL. This is therefore reported as a novel outcome.

All participants in the experimental groups who achieved the MCID in the SGRQ had their results re-evaluated to determine what were the predictors of improved HRQoL in this sample. This subset (n=22) was found to be normally distributed (skewness = -0.38) and became the proposed dependent variable for the multiple regression analysis. However, this subset being less than 30 was identified to be too small for a regression analysis based on reported guidelines (Stevens, 1996). Instead, Figure 5.10 had identified a number of significant correlations between HRQoL and other variables evaluated within this project.

The three experimental groups all achieved statistically significant and sustained gains in HRQoL. A statistically significant improvement as measured with the SGRQ following PRP attendance of various duration and follow up have previously been reported (Foglio, 2001; Griffiths, Burr, & Campbell, 2000; Ketelaars, Abu-Saad, Schlosser, Mostert, & Wouters 1997). The CDSMP group results in this project are in contrast to other behavioural studies in COPD that had utilised the SGRQ as an outcome measure. These behavioural studies were unable to report any health gains (Watson et al., 1997) or were limited to short term follow up (Bourbeau et al., 2003).

Not surprisingly, different intervention groups excelled in the different subscales. In the SGRQ subscale Impacts, the CDSMP group were the only group to maintain the MCID in this subscale. The CDSMP encourages participants to utilise strategies to minimise the impact of their condition and this result would suggest this intervention achieved its aim. The Activities domain, reports the effect of dyspnoea on function (Cullen & Rodak, 2002; Hajiro et al., 1998b; ZuWallack, 2003). Not surprisingly, the PRP and PRP+m groups were the only groups to maintain the MCID in the subscale. In the Symptoms subscale the PRP+m were the only group to maintain the MCID in this category. Reports in the literature above had identified that benefits in HRQoL from a six-week PRP are sustained for 12 months (Griffiths, Burr et al., 2000b) while PRP+m offered the greatest benefit (Vale et al., 1993). The results of this project would suggest that all three interventions confer statistically significant and clinically important sustained benefits to 12 months as evidenced in HRQoL scores.

Whether outcomes differ by gender is a topical area of interest in COPD health planning as little is published. Most of the HRQoL data in COPD has been studied only in men (Foy et al., 2001) due to a historically greater prevalence (Domingo-Salvany et al., 2002). Despite no statistical significant difference by gender or group by week 52, the results reported were quite inconclusive and varied between subscales (Appendix 5.25). Further COPD studies would need to include an equal number of women as participants and evaluate results additionally by gender to confirm whether gender is not an influence on health outcomes in COPD.

In summary, the null hypotheses that there would be no difference between all four groups in HRQoL by week seven through to week fifty two and by gender is rejected.

6.5 Self –efficacy

The *a priori* role self-efficacy was afforded in the conception of this project was described in Chapter Three of this thesis and tested in Chapter Five. At baseline, there was no statistically significant difference in self-efficacy between groups P=0.38. The baseline levels of self-efficacy as measured with the GSES-12 across all groups were high: (Figure 5.9). A ceiling effect on outcomes was anticipated but, both of the six-week intervention groups reported an equivalent improvement in self-efficacy by three units (7%) post intervention. There have been earlier reports in the literature of a nurse led self management program conferring significant (P<0.001) improvements in self efficacy in participants with COPD (Zimmerman, Brown, & Bowman, 1996). However the candidate was unable to find any reports of a behavioural intervention versus a rehabilitation intervention in a COPD sample demonstrating an equivalent increase in self-efficacy.

The literature review reported a moderate correlation between exercise capacity and self efficacy in PRP participants (Lox & Freehill, 1999; Scherer & Schmieder, 1997; Scherer et al., 1998). In this project's initial six-week experiment, both groups had recorded a significant pre-post intervention improvement in exercise capacity (P<0.01) and self-efficacy (P<0.01). However, no correlation was identified between these two variables by week seven (P=0.98). An increase to the order of seven percent in comparable domains such as HRQoL, is considered to articulate with a minimal clinical improvement (Osborne, 2003). With no known MCID for the GSES-12 the 32 study participants who recorded an increase in their week seven GSES Total Score of > three units (7%) were re-examined. This subset was normally distributed (skewness = 0.011) and, became the dependent variable to identify what combined features best predict an increase in self-efficacy.

Multiple regression was unable to define a linear model from a combination of this project's social, demographic, physiological or psychological variables that could explain an increase in self efficacy by three units, as limited by the available sample size. Simple regression was conducted to investigate

variables that may predict an improved GSES score. The results indicated that Depression at week seven was statistically significant F (1,75)=6.22, P=0.02. However, the adjusted R squared value was 0.06. This indicates that 6% of the variance in GSES was explained by depression which is a small effect size (Cohen, 1988). Figure 5.10 depicted the correlations and significance of relationships between all variables in this project. This would suggest that self-efficacy was not an important mediating variable in this project's COPD sample.

Longitudinal evaluation reported at week 52 a significant improvement in self-efficacy over time F (3,171)=4.69, P = 0.004 with no difference by gender or group F (6,112)=. 88, P=0.51. All groups had returned to their baseline levels of self-efficacy at week 52. This suggests that all three interventions conferred an effect yet the effect was not sustained once participation in any of the interventions had ceased. This is not a surprise finding as this project could not report a significant relationship at week 52 between self-efficacy with either HRQoL, exercise capacity or symptom control: (Figure 5.10). Whilst the literature has established these correlations exist (Kaplan et al., 1984; Scherer & Schmieder, 1997), these studies did not follow up participants over the duration. Pleasingly, these results suggest that improved self-efficacy can occur with participation in either a behavioural or, exercise therapy intervention for people with COPD

This project's group mean return to baseline when the tridactic reciprocal relationship of environment, behaviour or person (as described in chapter three) was not sustained, is not a surprising result. Performance accomplishment had been identified as the most influential source of personal efficacy (Conn, 1998). This project had identified that the only significant correlation was between self-efficacy with depression: Figure 5.10. Previous reports had suggested that the utility of the GSES-12 would be as an adjunct to measure for behavioural change (Sherer et al., 1982). It is possible that if this study had utilised a different self-efficacy measure the relationships between self-efficacy and the other dependent variables in this project may have unfolded differently. In summary, the null hypothesis that there would be no

difference between groups by week seven through to week fifty-two and by gender in accepted.

6.6 Costs of care

The AIHW had reported that in the time frame when the interventions for this project were being implemented the average cost of healthcare per Australian resident was $AUD3,397.00. The costs of care in this project were limited to calculating the direct costs. Indirect costs were not calculated as most of the study's participants were retired. Intangible costs had been identified as the reporting of symptoms and QALYs which are undertaken in other section of this chapter. The costs by intervention group amounted to $2860.30, $3952.98, $5589.79 for the CDSMP, PRP, PRP+m groups respectively. The costs of care in this analysis are limited to hospital and intervention costs and do not take into account medication or home care assistance. While the costings of the intervention groups are quite limited, these figures help to illuminate the significant cost burden a chronic illness such as COPD can generate.

The literature review had identified when conducting costs of care analysis that the benefits derived may not always be fiscal (Price, 2001). In this project HRQoL, functional capacity, self-efficacy and symptom control were significantly improved. Improvements in these health outcomes does not yield a monetary value. These results support the notion that economic evaluations should not be appraised independently of the clinical project (Dixon et al., 1999) and the interventions need to be satisfying to the staff and patients despite no reduction in costs of care (Price, 2001).

This study undertook two different approaches for the economic evaluation. The results had identified that the CDSMP, PRP, PRP+m all generate a significant improvement in health outcomes. As all three interventions recorded no significant differences in health resource use and the CDSMP was clearly the most cost effective intervention followed by the PRP and PRP+m.

The CUA is recognised as a two dimensional analysis that compared all reported costs against the group mean utility scores and modelled life time costs and life expectancy. These results were quite interesting as the utility value of the control and three intervention groups met the MCID in the AQoL measure (Hawthorne & Osborne, 2005). This finding is consistent with three of these four groups recording an equivalent improvement in their group mean utility score at week 52. The primary incremental cost effectiveness ratio between the PRP and PRP+m groups demonstrated a stronger patient preference for the PRP+m intervention but at more cost to society. The interpretation of the ICER suggested that $AUD 3156.65 would be saved for every QALY lost to the PRP+m intervention. This would be quite a difficult saving as the baseline QALYs are not large to begin with. For a health facility to implement a service such as maintenance, PRP would most likely result in an opportunity cost for existing services if additional funding could not be found.

The mean utility value for the PRP groups at baseline was 0.62, which meant that approximately 60% were reportedly enjoying good health. By week 52, this figure had increased to 0.72 for the PRP+m group. In contrast, just under half of the PRP group were enjoying good health (0.49) by week 52. When these results are compared with the modelled CUA the degree of difference between the two groups is comparable with the expected QALYs calculated to be 0.34 for the PRP group and 0.50 for the PRP+m group. These are high levels of QALYs when the calculated life expectancy generated was found to be extremely poor.

The economic evaluation in this study has confirmed the idea that health services need to be provided to optimise the health of the participant. This study demonstrated that all interventions recorded improvement is physiological and psychological health. However no intervention was able to clearly demonstrate less use of hospital resources which have long been recognised as the largest cost of care for people with COPD.

6.7 Limitations of this project

6.7.1 Internal validity

This project attempted to protect internal validity at the design stage of the study by having a non-intervention comparison group and longitudinal evaluation (until week 52), rather than a cross sectional study design. Chapter Four outlined the role of the candidate in this study. Where one nurse conducts all of the experiments with a structured protocol that can be used by others, this has been reported to reduce the variance of the treatment between subjects, increase the internal validity and give a higher probability of the reproducibility of the experiment (Carrieri-Kohlman et al., 2001).

Threats to internal validity have been reported to include "history, maturation, testing, instrumentation, mortality and selection bias" (Beanland et al., 2000 ,p.184). These threats were minimised as described below.

The utility of a randomised design allows extraneous variables to be spread across all groups (Beanland et al., 2000; Beller et al., 2002; Hopkins, 2000). The study design was therefore able to offset history as a risk in this project. Maturation with time in study participants and repeated testing with the same questionnaires can compromise the internal validity of a study (Beanland et al., 2000). These threats were reduced by the inclusion of a control group to compare results over time against. Mortality and attrition from this study was reported in the flow charts presented in Chapter Five. Reporting on all those enrolled in the study reduces bias in presenting results that exclude the non completers (Heritier et al., 2003)**.** Finally, selection bias was probably the most difficult threat to minimise. Despite the stringent method of randomisation, this project used seed envelopes for the randomisation process. This method may not be regarded as secure randomisation by some and is therefore reported as a study limitation. While the selection of a seed envelope is recognised as a basic method of randomisation, study constraints meant that it was not possible to engage any other method of randomisation. To reduce selection bias recruitment for this project was extended to two years (in addition to the one year follow-up) to ensure the project was sufficiently powered to test the null hypothesis of no difference between groups with

respect to HRQoL and functional status. This period of recruitment was twice as long as initially planned due to the low uptake to the project. There had been a report in the literature of participation in a study as compared to all those who were screened to be as low as 1 in 3 (Ringbaek et al., 2000), which was consistent with uptake to this project. To evaluate for selection bias the study cohort from Hospital A was compared with all those admitted to Hospital A with an exacerbation and no significant differences were reported by age, prevalence of pre-existing medical co-morbidities or gender, as described in Chapter Five.

6.7.2 External validity

The effects of selection, testing and reactivity are recognised as treats to external validity in any research endeavour (Beanland et al., 2000). Barriers to study participation were reported to be both logistic and discretionary and have been summarised:(Table 5.1). These barriers were consistent with earlier reports (BTS, 2001; Evenson & Fleury, 2000; Hellman & Williams, 1994; Pepper-Burke, 2003; Young et al., 1999). Table 5.1 reported the number of referrals to the study who were deceased within five weeks of hospital discharge following an exacerbation. This outcome suggests that clinician selection and referrals to the study may have been skewed to simply those most apparent with the condition. To discount this threat a comparison between the study participants and all those admitted to Hospital A with an exacerbation was undertaken and discussed in this thesis.

While literacy in English was necessary as an inclusion criteria it was additionally a barrier to wider recruitment for this project. Generalisability of the results cannot be assumed to be equally applicable to non-English speaking COPD patients. There have been at least one report that has identified ethnicity as a limitation in interpreting HRQoL results in patients with COPD (Katsura et al., 2007). Study participants who are tested with repeated measures over the duration risk recording a response shift. This changing of internal values and self perception has been reported to occur in chronic illness studies involving HRQoL questionnaires as participants learn

new skills and/or alter their self talk (Sprangers & Schwartz, 1999). In addition, when one nurse conducts all of the interventions and assessment tests, this dual role has been reported to decrease the external validity of an experiment (Carrieri-Kohlman et al., 2001). However, the addition of a control group to this project enabled the true effect of the interventions to be compared against the reactive effects being studied.

6.7.3 Project strengths

This is the first study to directly compare the effect of the six-week Stanford model CDSMP with a six-week PRP over a number of health outcomes in COPD. The effect of maintenance PRP as compared to a six-week PRP was an additional project evaluated along with an examination of the effect of gender on health outcomes and within groups. This project was an efficient way to explore the effects between and within groups despite adding complexity to the design and data analysis. This study therefore represents a unique and significant contribution to existing knowledge.

This study was a randomised study with longitudinal follow up. The merit of a randomised design was highlighted in Chapter Four of this thesis. The inclusion of a control group enabled the true measure of the effect of interventions to be compared with a group of fellow COPD patients who reported comparable baseline characteristics as tabled in Chapter Five. The use of validated and ubiquitous outcome measures was an advantage for this study. All outcome measures were simple to understand and enabled self-completion of questionnaires by the study participants. Dyspnoea and fatigue are recognised symptoms that people with COPD constantly live with. Having simple, brief questionnaires to complete may have contributed to the high response rate (75%) of participants at week 52.

There is always a risk of selection bias with a study cohort being limited to motivated individuals who volunteer or those who are identified by their physicians. An extensive audit of all those who were admitted to Hospital A with COPD during the period of recruitment were compared with the uptake to this study and no significant difference was found by age, gender, pre-existing

health issues or with the Control group from Hospital B. This would again suggest that this study's results are most likely representative and generalisable to both Hospital's cohort of English speaking COPD patients.

This project's strengths included the prospective application of a conceptual model to frame the delivery of the interventions, which we have reported (Murphy et al., 2005; Murphy et al., 2003). Additional strengths include 90% of the PRP group had completed the six-week intervention. This low rate of attrition is consistent with an earlier report (Katula et al., 2004). Due to the low rates of attrition, data was collected on the vast majority of all study participants at every time point during the 12 months of the study:(Table 5.1), which became a significant strength for this project.

The rate of attrition from the maintenance as compared to a six-week rehabilitation program was much greater (33 vs. 10%). However the rate of attrition is less than reports from other studies (Elliott et al., 2004; Foglio, 2001) which must be regarded as a strength. Reasons offered for attrition from the PRP+m were summarised in Appendix 20 and are similar to current reports of attrition (Fischer et al., 2007) Despite PRP+m participants continuing to be hospitalised for an exacerbation, once recovered they returned to the PRP+m intervention and kept exercising. The literature review had identified criticisms of maintenance PRPs (PRP+m) on the basis that the progressive nature of COPD and occurrence of exacerbations impacts on the ability to sustain a (new) active lifestyle, and long term maintenance had been speculated as therefore unlikely (Bestall et al., 2003). This study's outcome is therefore a welcome contrast to other studies (Brooks et al., 2002) and, is consistent with reports that longer term programs support behaviour change (Spruit et al., 2004).

6.8 Summary

The research showed that functional capacity could be significantly improved by a non PRP intervention in people with COPD. In addition, neither six-

week intervention conferred greater HRQoL than the other. There was some variability between groups over the duration of benefits in different outcome measures but gender was not an influence on outcomes by group or over time.

My study has a number of caveats. Possible sources of bias were the necessity of being literate in English to enable participation in the study, the limitations of the available Control dataset at the time of writing and analysis was initially filtered to all those who attended nine out of twelve PRP sessions or 4 out of six CDSMP sessions. These issues may have influenced some of the outcomes. The project's limitations were categorized and discussed as threats to internal or, external validity. The strength of the project includes the use of a randomised design with long term follow up using validated instruments. The prospective collection of data and a cost analysis were also strengths in this project. The calculation of costs illuminated the costs of care in COPD are greater than the population norm. In addition, maintenance PRP generated a greater QALY than a six-week program. Despite the strength of the patient preference (as measured by the QALY) for maintenance PRP, there were no significant differences in use of hospital resources throughout the study period by the three intervention groups, which suggests some degree of equivalence.

The next Chapter concludes this project and suggests areas for future research.

Chapter Seven Conclusion

7.1 Review

The primary aim of this thesis was to implement and evaluate the efficacy of nurse led interventions in the ambulatory care setting for people with COPD. Creating and implementing multiple interventions was not without its challenges. The process of implementing these programs enabled a conceptual health model to be prospectively applied to the interventions with the ambition that a philosophical underpinning might generate added benefit. As a result of implementing all of these interventions our measurements of health outcomes have resulted in a number of novel outcomes.

The CDSMP program when evaluated at week seven was able to demonstrate an effect in functional capacity, HRQoL and self-efficacy. The statistically significant improvement in functional capacity and HRQoL by the CDSMP intervention using standardized measures was this project's novel finding.

The literature review undertaken for this thesis gave rise to the idea of evaluating the programs by gender, as little had been published despite the increasing prevalence of COPD in women. When the results were analysed by gender no statistically significant differences were identified in almost all measures. HRQoL was however, the only measure where there was an inconsistent result by gender that varied within each of the subscales of the St George Respiratory Questionnaire but not in the overall total score.

An exacerbation of COPD and functional status have been recognized as indicators of disease progression. This study has demonstrated that the incidence of emergency department presentations and hospital admissions for an exacerbation of COPD were not statistically significantly different between the three intervention groups. Health resource use between the intervention groups was similar. The QALYs for each intervention group suggests that this cohort experienced at best a fair state of health and as a result, a reduction in hospital resource use would be unlikely.

This study has demonstrated that an improvement in functional capacity does not necessarily articulate to an improvement in weekly functional performance. In this cohort of study participants, participation in either a six-week or six month PRP or the CDSMP did not appear to offer a greater advantage over the other. This suggests that the process of the intervention may well be just as critical as a program's content and duration. For people with COPD who cannot exercise due to other ailments this is a welcome finding.

7.2 Implications for treatment and further studies

The prevalence of COPD is expected to climb (Murray & Lopez, 2002) and with it the need to access proven treatments. Despite the increased need for COPD management at Hospital A referrals to pulmonary rehabilitation were limited in number and included those with end stage COPD who then proceeded to die within five weeks of their referral. Therefore I would suggest that clinical staff need to increase their adherence to the clinical practice guidelines for COPD in the acute and ambulatory care setting and consider referrals to adjuvant therapies earlier in the disease process to optimise benefit (ATS, 1995b; BTS, 1997; Clinical Evaluation and Health Service Evaluation Unit, 1999; McKenzie et al., 2003). PRPs should no longer "be viewed as a last ditch effort for patients with severe respiratory impairment. Rather it should be an integral part of the clinical management of all patients with chronic respiratory disease" (Nici et al., 2006 ,p1390).

I have demonstrated that the Stanford model CDSMP is a valid treatment for people with COPD that significantly improves exercise capacity and generates both a significant and clinically important difference in HRQoL when assessed with standardized measures. Despite both the PRP and CDSMP interventions demonstrating significant and clinically important improvements, the degree of benefit tapered off by six months. Further research is therefore urgently needed to identify treatments that generate longer term efficacy and also include participants with limited literacy in English.

A prospective controlled trial with usual weekly attendance at the Stanford CDSMP followed by twelve-weekly sessions in a PRP should be undertaken. Twice-weekly PRP attendance has been recognised as the minimum standard (BTS, 2001) for a stand alone treatment. Few reports have advocated a once a week PRP (O'Neill et al., 2001). However, my clinical experience is that non PRP therapies such as the CDSMP can also generate a statistically significant increase in functional capacity and equivalent functional performance and improvement in HRQoL in people with COPD when compared to a twice weekly, six-week PRP. A combination of the two programs should halve the cost of PRP provision and enable twice the volume of people with COPD to access the gymnasium based component which, would then help with the chronic issue of reported low accessibility (Crockett et al., 2002; Nosworthy et al., 2001).

Selection criteria could be similar to that of this project and, as such no participant would have to wait in a control group for 12 months. This proposed study could examine a number of aspects of the efficacy of treatment. These may include,

- rates of referral, participation and attrition,
- effect of therapy on functional status, symptom control (dyspnoea, depression)
- HRQoL
- Health care utilisation data, especially the effects on emergency department presentations, hospital admissions and their length of stay.

Other options for future research could include:

- A clinical trial that investigates combinations of PRP exercise strategies in tandem with the weekly CDSMP program. Possible combinations could include a weekly six-week lower limb exercise training program with the six-week CDSMP, a six-week upper limb exercise training program with the six-week CDSMP and/or a six-week, weekly interval training program with the six-week CDSMP. These combinations may inform which PRP exercise program delivers optimal results with the CDSMP program on functional

status, HRQoL, symptom control and health resource utilization over a 12 month period.

- A randomised controlled trial that investigates a twice-weekly six-week PRP with tele-support. The six-week PRP could then be followed by weekly telephone contact until week 52 to identify whether participants are meeting their exercise targets and optimising their symptom control as compared to participants in a twice-weekly six-week PRP. This clinical investigation could be evaluated at baseline, post program at week seven and week 52 in domains of interest such as functional status, HRQoL, symptom control and health resource utilization over a 12 month period of follow up.

- A formal analysis of barriers to attend outpatient based programs for people with COPD. This would add to our understanding of obstacles patients experience in accessing therapeutic interventions especially as the reports on barriers to rehabilitation attendance have concentrated on cardiac rehabilitation programs.

- The current study has demonstrated that a generic behavioural program offers health benefits to people with COPD. Cardiac disease has been reported to often co-exist with COPD (Huiart et al., 2005; Schroeder et al., 2003; Sin & Man, 2003). Furthermore, all chronic diseases are recognised to generate similar challenges and concerns (Lorig, Sobel et al., 1999). A clinical trial that compares the effect of participation in the six-week CDSMP followed by randomisation to either a disease specific rehabilitation program (i.e. a six-week PRP) or a six-week exercise program for people with cardiovascular disease with 12 month follow up. This study could be evaluated over similar health outcomes to the present study. This would inform whether a disease-specific exercise program is necessary and, if the CDSMP program as a precursor to a rehabilitation program fosters a culture of goal setting, weekly evaluation of targets to achieve and health gains beyond six months.

In addition to clinical research studies, further studies are required to evaluate if PRP graduates who demonstrate improved exercise capacity also improve their lung function. Previous reports had identified a strong correlation between spirometry and functional status (Belza et al., 2001; Myint et al., 2005; Oga et al., 2002; Schonhofer et al., 1997). This would add to the understanding whether exercise training can improve respiratory function and not simply the perception of respiratory symptoms such as dyspnoea.

The candidate has shown that not participating in a therapeutic intervention leads to a continued deterioration in functional capacity. This is an important outcome as functional capacity had been identified in two COPD studies (in Chapter Two) as a greater prognostic indicator of survival post rehabilitation program attendance than gender, BMI or, social status (Bowen et al., 2000; Gerardi et al., 1996). This research project provides a basis for further studies, which may lead to an improvement in the health and quality of life of people disabled by this chronic condition.

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Appendix One

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up Maintenance
Griffiths et al 2000, Wales	**Outpatient** *Education + Ex vs. Usual Care* N=200 99 I: 101 C	6 weeks	3 x week	Commenced at 80% Vo2 max from ISWT baseline results	Lower Limb Exercise (LLE)	ISWT SGRQ SF-36 CRDQ HAD Hospital Admissions Medication usage Primary Health care usage	Intervention group: no statistical significant improvement in exercise tolerance, Reduced length of stay for intervention group with respiratory illness vs. control (p=0.02) Rate of Readmission for respiratory illness equivalent in both groups (p=0.98), QoL equivalent in both groups, ↓use of some inhaler medications by intervention group (p=0.004)	12 months
Reardon et al 1994, USA	**Outpatient** *Education + Ex vs. Usual Care* N=20 10I: 10 C	6 weeks	2 x week	70-85% HR max or symptom limited (dyspnoea)	LLE	BDI/TDI Graded Treadmill test Visual Analogue Scale RFT's	Reduction in dyspnoea (p<0.02)	Unspecified
Ringbaek et al 2000 Denmark	**Outpatient** *Exercise vs. Control* N= 36 24 I: 21 C	8 weeks	2 x week	unspecified	Lower limb, Upper Limb exercises,	6 MWT SGRQ PGWB RFT's Borg score	No significant improvement in exercise tolerance or well-being	nil

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up Maintenance
Ries et al 1995 USA	**Outpatient** *Education vs. Exercise* N=119 62 Ed: 57 Ex	8 weeks	12 sessions over 8 weeks	Symptom limited	Lower Limb Exercise, Education, Psychosocial Support	Self efficacy for walking, RFT's Dyspnoea, HRQoL, Mortality rate Hospital LOS	Compared to the education only group, The Ex group reported Increased Ex tolerance (P<0.001), Reduced dyspnoea (P<0.01) Self efficacy (P<0.05) Equivalent Survival (P=0.32), Hospital LOS (P=0.2)	6 Year Follow up
Lake et al 1990 Australia	**Outpatient** Exercise strategies (x3) Vs. Control N= 28 20I: 8C	8 weeks	3 x week	unspecified	Combined Lower limb + Upper Limb exercises or Lower limb or Upper Limb only	6 MWT Cycle + arm Ergo meter Tests Bandura scale wellbeing RFT	Control: no significant change Improved exercise tolerance in all intervention groups, Combined Intervention group achieved most gains in ex tolerance and well being	Unspecified
Bendstrup 1997 Denmark	**Outpatient** *Education + Exercise vs. Usual Care* N=32 16 I: 16 C	12 weeks	3 x week	unspecified	LLE, ULE, Inspiratory Muscle training,	6 MWT CRDQ York QLQ RFT's ADL score	Significant improvement in the intervention group in 6MWT and ADL (p<0.004)	6 months

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up
Sassi – Dambron et al 1995 USA	**Outpatient** Education vs. usual care N= 89 I 46:C43	6 weeks	1 x week	Not applicable	Education Relaxation Breathing techniques Self Talk Panic Control Stress Management	BDI / TDI ATS Dyspnoea scale Oxygen cost diagram SOBQ VAS Borg QWB STAI CSED	No significant difference between intervention + control at week 6, or 6 months	Ni
Berry et al 1996 USA	**Outpatient** Control vs. General Ex vs. General Ex + Inspiratory Muscle Ex N=25 16I : 9C	12 week	3 x week	Walking intensity: 50-75% pt's HR reserve	LLE ULE Inspiratory Muscle Training	12MWT, Borg score Dyspnoea,	Control group:NSC Intervention: Inspiratory Muscle training + General Exercise conferred no additional benefit beyond general exercise	Nil

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up
Strijbos 1996 Netherlands	**Outpatient vs. home based** Pulmonary rehabilitation vs. Usual Care N= 45	12 weeks	2 x week	Up to 70% peak work rate	Lower limb exercises,	4MWT Cycle Ergometer Test RFT's	Significant improvement in the intervention groups with benefits in home based greater after 6 months	Benefits maintained for 18/12
Cambach et al 1997 The Netherlands	**Community Based** N= 66 37C: 29I Both asthmatics & COPD patients	12 weeks	3 x week	60% Wmax workload max	Breathing Ex, Education, ULE, LLE	Incremental cycle ergometer test, Endurance cycle ergometer test, 6MWT, CDRQ,	Significant increase in cycling ability until Week 12 , the MCID not met with COPD pts in 6MWT, Improved QoL retained at 6 months	Nil

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up Maintenance
Weiner et al 1992 Israel	**Outpatient** General exercise vs. general ex + inspiratory muscle training (IMT) vs. control N= 36,12 each group	6 months	3 x week	5% increase in cycling resistance each session up to 50% baseline assessment	ULE, LLE, Inspiratory muscle training	12MWT Respiratory Muscle strength	No difference in intervention groups in the outcome from the walking test IMT in addition to exercise demonstrated improved inspiratory muscle strength	Not stated
Simpson et al 1992 Canada	**Outpatient** Weightlifting training vs. Control N= 28 14I:14C	8 weeks	3 x week	Not specified	ULE, LLE	6MWT RFT'S Quadriceps strength Handgrip strength Progressive cycle ergometer test CRDQ Borg	Intervention group: no significant improvement in walking, Significant improvement in CRDQ in the domains of dyspnoea and mastery	Not stated

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up Maintenance
Cockcroft et al 1981 UK	**Inpatient, then home based** Exercise vs. control N=34 18I:16C	6 weeks	Daily	Not specified	ULE, LLE	12MWT Pt activity Diary (intervention group only)	Significant increase in walking distance ($p<0.05$) by intervention group	7 months – treatment group only
Goldstein et al 1994 Canada	**Inpatient and outpatient based** 8 week inpt Intervention +16 week outpt vs. Control N= 79 I38:C41	24 weeks	3 x week	Not specified	Warm Up Exercises, ULE LLE, interval Training Education Psycho social support	6MWT CRDQ BDI/TDI	↑ Exercise Tolerance ($p=0.007$) ↓Dyspnoea ($p=0.005$) ↑ emotional function ($p=0.01$)	24 week follow up

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up Maintenance
Booker 1984 UK	**Outpatient** Control vs. LLE vs. LLE + Psychosocial support N=128	9 weeks	Unspecified	Maximum of 15'	Stair climbing vs. LLE + Breathing Ex, postural drainage, relaxation	6MWT Pt completed activity diary	No clinically significant differences between the three groups	12 months
Wijkstra 1994 Netherlands	**Home Based** Education + Ex vs. usual care N=43 28I:15C	12 weeks	2 x week	Up to 76% peak work rate	LLE ULE inspiratory muscle exercise	CRDQ Cycle ergometer Test RFT's	Intervention group: No change in RFT's ↑QoL ($p<0.001$) ↑cycle performance ($p<0.05$) Improved QoL was not associated with improved Ex Tolerance	Unspecified

1st Author, Year, Country	Program location & investigation	Program duration	Frequency	Intensity	Program content	Outcome Measures	Results	Follow up Maintenance
Clark et al 1996 UK	**Home based** Intervention vs. control N= 48 32I:16C	12 weeks	Unspecified	Not specified	ULE, LLE	Endurance Walk Test RFT's Cycle ergometer UL + LL muscle endurance	Endurance Walk Test I vs. C ($p<0.001$) No change in RFT's in either group, Intervention group: ↑UL + LL muscle endurance ($P<0.001$)	Unspecified
Norweg et al 2005 USA	**Outpatient based** 3 interventions: Ex; Ex+activity; Ex +education N=43	10 weeks	Twice weekly	Exercse intensity Titrated to Borg scores	ULE,LLE Postural drainage, lectures	6MWT CRDQ, PFQ, COPD Self-Efficacy scale	Equivalence in exericise tolerance and self efficacy between groups	Six months

Appendix Two

ACU National
Australian Catholic University
Sydney Canberra Ballarat Melbourne

THE NORTHERN HOSPITAL

Plain Language Statement

Version 1.3

Site: The Northern Hospital

Full Project Title:

A randomised controlled trial of the effects of a patient Self Management program compared with a Pulmonary Rehabilitation Program in Chronic Obstructive Pulmonary Disease on physiological, psychological & economic outcomes in North West Melbourne.

Principal Researcher: A/Professor Bruce Jackson

Associate Researcher(s): David Berlowitz, Maria Murphy, Karen Page and Katherine McCann.

This Plain Language Statement and Consent Form is 5 pages long. Please make sure you have all the pages.

1. Your Consent

You are invited to take part in this research project.

This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the Statement.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form you do not alter your legal rights, but you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of both the Consent Form and this Plain Language Statement to keep as a record.

2. Description of the Project

The purpose of this project is to determine the effects of attending an exercise program or, a chronic disease self- management program, designed for people with breathing problems like your own. In particular, we would like to determine if attendance at an exercise program "Pulmonary Rehabilitation" or, a patient Self Management program will improve a person's quality of life, ability to exercise and reduce their use of health services. Using this information, we would then like to establish what is the most cost-effective way of managing people with lung disease in our community.

A total of 180 people will participate in this project. 90 people will be enrolled from The Northern Hospital, Epping and 90 people enrolled at The Western Hospital, Footscray.

Previous experience has shown that attendance at pulmonary rehabilitation can improve a person's functional ability and the quality of their life but as yet we are unsure if this reduces a persons need to use health care services. The Self Management program has not been assessed in people with lung disease in Australia.

The study requires your participation for one year. Participation in this project will involve attending the assessment sessions plus a 6 – week Self-Management Program at The Northern Hospital *or*, a 6-week Pulmonary Rehabilitation alone *or* the 6-week Pulmonary Rehabilitation program at the Northern followed by weekly Pulmonary rehabilitation in the community for a further 19 weeks. Patients enrolled from the Western Hospital will attend the six week exercise program alone.

You will need to continue to attend your regular medical appointments. The current standard of care you are receiving will not change when you are enrolled in the project group. At the end of your participation, you will be offered a place in the exercise or Self Management Program should you wish to take up this option. This way, you can participate in both programs if you wish to.

You may also be asked to attend a "Lung Function Test" if you have not completed one in the last twelve months. This test involves blowing into a machine. An inhalation medication will then be given to you and the breathing test is repeated. The Lung Function Test needs to be done only once, at the beginning of the study. This test will involve no cost to you.

All participants in the study will need to attend 4 assessment sessions over a 12-month period. You will be contacted by mail to notify you of when the assessment session will be. The assessment sessions will be approximately 2 hours in duration. After an initial assessment, assessment sessions are repeated at 6 weeks, 6 months and 12 months. The following activities will be completed when you attend the assessment session.

Walking Test:

You will be asked to complete two walking tests. The test involves walking around two cones at a speed determined by an audiocassette. You will have a 20-minute break between the walking tests. Before and after the test, we will

measure your breathing rate, heart rate and blood pressure. We will also measure the amount of oxygen in your blood using a device that clips onto your finger.

Questionnaires:

There will be some questionnaires to be completed. It is expected that these questionnaires, will take approximately 40 minutes in total. The questionnaires will ask you about how your breathing problems affect you in your everyday activities.

One week before attending each assessment session, you will be sent a diary in the mail that will need to be kept for one week. In this diary information about the following should be recorded:

1.The medicines and health products you use in that week

2. The health and community services you use in that week

The diary will be collected from you when you attend the assessment session.

Depending on which intervention you are randomised to,

you will need to attend the Self Management Program once a week for 6 weeks, or the Pulmonary Rehabilitation Program twice a week for 6 weeks or 6 weeks of Pulmonary Rehabilitation twice a week followed by 19 weeks of once weekly Pulmonary Rehabilitation. Each class runs for approximately 2 hours in duration.

3. Possible Benefits

We cannot guarantee or promise you that you will receive any benefits from this project but, there is good evidence to suggest your quality of life, ability to exercise and confidently manage your condition may increase. Your participation in the project may also allow other patients with breathing problems like your own, to access such a program in the future in the Northern and Western suburbs of Melbourne.

4. Possible Risks

There are few risks associated with the project. A possible risk in this study is that of sustaining an injury while performing exercise or during the assessment procedure, ie: muscle strain. The potential for any injury to happen in the program or assessment session is very small. In the unlikely event that your breathing problem is exacerbated, back up respiratory care will be available if required.

You can suspend or end your participation in the project if distress occurs.

5. Confidentiality and Disclosure of Information

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law.

To assess the how you use health care services, it is planned to obtain information from the Health Insurance Commission on the number of visits

you have to your local doctor and the medication prescribed to you during the study period.

If you are admitted to the hospital for breathing problems during the study period, an examination of your medical record will be performed. Information will be collected on how bad your breathing was when you were brought to the hospital, how long you stayed in hospital for and what treatment you received while you were in hospital.

Your permission for us to obtain this information is given by signing the Consent Form.

In any publication, information will be provided in such a way that you cannot be identified. Results will be aggregated which in no way identifies the individual subjects.

7. New Information Arising during the Project

During the research project, if any new information about the risks and benefits of the project may become known to the researchers, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

8. Results of Project

On completion of the study, a final report will be provided to the Northern and the Western Hospitals. Publication of the outcomes will be the decision of each participating organisation. The study results will also be submitted for publication in scientific journals.

An article may be submitted to the local newspaper to report on the project outcomes.

These documents will not contain individual data but will describe the difference between the two groups of participants.

9. Further Information or Any Problems

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the principal researcher Associate Professor Bruce Jackson. The researchers responsible for this project are:

Principal Researcher:

A/Professor Bruce Jackson	Tel:	8405 8721

Associate Researchers:

Mr David Berlowitz	Tel:	8405 8480
Ms Maria Murphy		8405 8014
Ms Karen Page		8405 8804
Ms Katherine McCann		8345 6661

10. Other Issues

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact

Name: Ms Jessica Beattie

Position: Clinical Risk Co-ordinator

Telephone: 8405 8046

You will need to tell Ms Beattie the name of one of the researchers given in section 9 above.

11. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Northern Hospital.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Only sign the Consent Form once you have had a chance to ask your questions and have received satisfactory answers.

Before deciding whether or not to take part, you may wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

12. Ethical Guidelines

This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The Clinical Research and Ethics Committee of the Northern Hospital have reviewed the ethical aspects of this research project.

Appendix 3.Topics covered in the six-week CDSMP.

Week	Purpose and Objectives
One	Differentiate between acute and chronic conditions, Introduction to cognitive symptom management and, Goal setting
Two	Problem Solving, Making an Action Plan, Dealing with the emotional sequelae of a chronic condition, Introduction to exercise
Three	Diaphragmatic & pursed lipped breathing, Fatigue management, Endurance exercise, Problem solving and Action planning
Four	Healthy eating, Distraction, Enduring Power of Attorney (medical treatment), Communication skills, Problem solving and Action planning
Five	Medication usage, Depression management, Self talk, Guided imagery, Making informed treatment decisions, Problem solving and Action planning
Six	Communication and working with the health care team, Planning for the future

Appendix 4

Northern Health

ACU National

Australian Catholic University
Brisbane Sydney Canberra Ballarat Melbourne

THE UNIVERSITY OF MELBOURNE

Pulmonary Rehabilitation Program

Home Exercise Record

The Northern Clinical Research Centre
The Northern Hospital
185 Cooper Street, Epping, Victoria, Australia, 3076
Telephone (03) 9219 8054 Facsimile (03) 9219 8683

Exercise Guidelines

- *Aim to exercise MOST days of the week to ' feel better' and to make exercise of benefit to you!*

- Aim to exercise at a pace that makes you **moderately breathless**
  3 or 4 on the Borg Scale

- Aim to achieve 30 minutes in total

This can be as much as 30 minutes in one go or, as little as 1 minute every hour that you are awake.

Pulmonary Rehabilitation classes in the gymnasium twice a week **together** with one exercise session at home each week will be of benefit to you.

(If you have the time to exercise more than once a week at home this will add to the benefit of exercise for you but a minimum of 3 exercise sessions in total is necessary to achieve the benefit we are all aiming for).

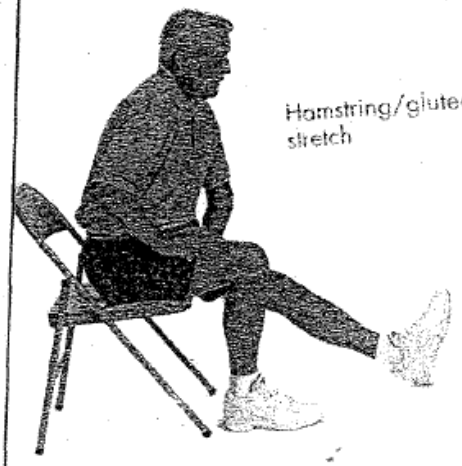
Warm up Exercises

Every one progresses at a different rate and you need to exercise at your own level, do not compare yourself to others.
Exercise should be moderately challenging but, you should still be able to walk and talk.
These warm up exercises should be done **slowly** and **gently**.

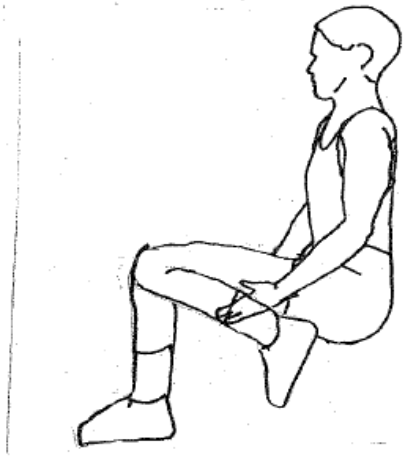
NECK STRETCH - lateral flexion
Tilt head to shoulder.
Repeat other side.

NECK STRETCH - Rotation
Turn head slowly to the side.
Repeat to the other side.

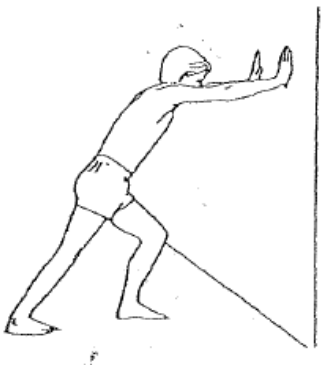
SHOULDER CIRCLES
Roll both shoulders in a backward direction, and then forwards



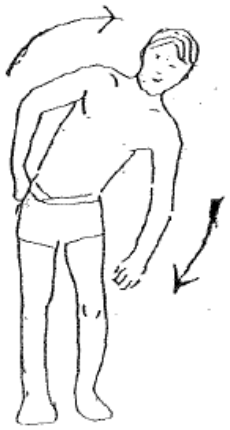
QUADRICEPS STRETCH
Pull your heel towards your buttock until a stretch if felt in front of the thigh.



CALF STRETCH
Keeping your back leg straight and front leg bent, lean into the wall until a stretch is felt in both calf muscles. You must keep both heels on the floor.



SIDE BENDS
Standing with legs comfortably apart, bend down to each side.



CHEST/ BICEPS STRETCH
Lace fingers behind your back and squeeze shoulder blades together. Gentle raise and straighten arms.

BORG SCALE OF Shortness of Breath

0 Nothing at all

0.5 Very, Very Slight

1 Very Slight

2 Slight

3 Moderate

4 Somewhat Severe

5 Severe

6

7 Very Severe

8

9 Very, Very Severe

10 Maximal

DATE NAME Exc diary. fe

STRETCHES see pages 3 & 4

WALKING

⇒Time Walked_____ minutes

⇒ Distance_____

Route_____

⇒ BORG Scale SOB_____

EXERCISE BIKE

⇒Riding Time _____minutes

⇒BORG SOB _____

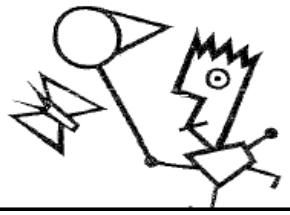
Scale/10 _____

OTHER EXERCISES

⇒Riding Time _____minutes

⇒BORG SOB _____

⇒Scale/10



Appendix 5 The Borg scale for the measurement of dyspnoea

BORG SCALE of shortness of breath

0	Nothing at all
0.5	Very, very slight
1	Very Slight
2	Slight
3	Moderate
4	Somewhat Severe
5	Severe
6	
7	Very Severe
8	
9	Very, Very Severe
10	Maximal

Appendix 6 The Borg scale of perceived exertion

BORG SCALE of perceived exertion

6

7 Very, Very light

8

9 Very light

10

11 Fairly light

12

13 Somewhat Hard

14

15 Hard

16

17 Very Hard

18

19 Very, very Hard

20

Appendix 7

MRC DYSPNOEA SCALE

The MRC *dyspnoea scale is a questionnaire that consists of five statements about perceived breathlessness:*

Please read the following statements and select that which most applies to you.

Grade 1	I only get breathless with strenuous exercise
Grade 2	I get short of breath when hurrying on the level or up a slight hill
Grade 3	I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level
Grade 4	I stop for breath after walking 100 yards or after a few minutes on the level
Grade *5*	I am too breathless to leave the house

Appendix 8

Trial Number
Baseline, Week: 7,24,52

The Hospital Anxiety and Depression Score

Doctors are aware that emotions play an important part in most illnesses. If your Doctor knows about these feelings he will be able to help you more. This questionnaire is designed to help your doctor to know how you feel. Read each line and underline the reply that comes closest to how you have been feeling in the past week. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.

I feel tense or "wound up":

Most of the time
A lot of the time
From time to time, occasionally
Not at all

I still enjoy the things I used to enjoy:

Definitely as much
Not quite as much
Only a little
Hardly at all

I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly
Yes, but not too badly
A little, but it doesn't worry me
Not at all

I can laugh and see the funny side of things:

As much as I always could
Not quite so much now
Definitely not so much now
Not at all

Worrying thoughts go through my mind:

A great deal of the time
A lot of the time
From time to time but not often
Only occasionally

I feel cheerful:

Not at all
Not often
Sometimes
Most of the time

I can sit at ease and feel relaxed:

Definitely
Usually
Not often
Not at all

I feel as if I have been slowed down:

Nearly all the time
Very Often
Sometimes
Not at all

I get a sort of frightened feeling like "butterflies" in the stomach:

Not at all
Occasionally
Quite often
Very often

I have lost interest in my appearance:

Definitely
I don't take so much care as I should
I may not take quite as much care
I take just as much care as ever

I feel restless as if I have to be on the move:

Very much indeed
Quite a lot
Not very much
Not at all

I look forward with enjoyment to things:

As much as I ever did
Rather less than I used to
Definitely less than I used to
Hardly at all

I get sudden feelings of panic:

Very often indeed
Quite often
Not very often
Not at all

I can enjoy a good book or radio or TV Programme:

Often
Sometimes
Not often
Very Seldom

Thank you for completing this questionnaire.

Appendix 9

Pulmonary Assessment:

please circle baseline, Week 7 24 52 Week 59

Date of Birth Trial No Date of Consent UR No

Circle where appropiate WNL= within normal limits

Patient Consent to Medical & Social History? ❒Y ❒N

Communication

❒WNL ❒ Understands English ❒ Speaks English
❒ Country of Birth ❒ Language spoken at home_____

Hearing

❒WNL ❒ Impaired Deaf: Unilateral / bilateral
❒Hearing aid with subject

Visual

❒WNL ❒ blind (*specify*……..) ❒ Prothesis
❒ Spectacles

Allergies: Foods or Medications *specify*……

Weight:_____ Height_____ BMI:_____

Respiratory Status:

How far can you walk?
What stops you?

Cigarettes: current smoker? ❒ Y ❒ N ever smoked? ❒ Y ❒ N
No. cigarettes day……..Age started smoking:……. Pack years:…….
Other Tobacco? ❒ Y ❒ N
Other Relevant Resp Hx…….

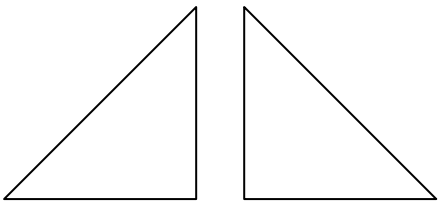
RESPIRATORY MEDICATIONS

Fluvax?
Pneumovax?

O2 THERAPY: ❒ Y ❒ N

Respiratory Assessment:

Breathing Pattern
Auscultation:
Sputum:
Cough:



RFT's: *Date of Test:*
FEV1: Predicted:
FVC: Predicted:

Exercise/ pulmonary rehabilitation history:

Musculoskeletal assessment:
Back Problems? ❒ N ❒ Y specify……..
Any Hx problems associated with Shoulders? ❒ N ❒ Y specify……..
Neck? ❒ N ❒ Y specify……..Lwr Limbs? ❒ N ❒ Y specify……..
ROM Limitations ?❒ N ❒ Y specify……..
Requires assistance with movement? ❒ N ❒ Y specify……..
Current Functional Level:…….
Can you bend over? What happens when you do?

Social history	*Problems with sleeping*	*Home help*
Lives Alone: ❒ N ❒ Y	❒ N ❒ Y *specify*……	MOW ❒ N ❒ Y
Primary carer: ❒ N ❒ Y	……	RDNS ❒ N ❒ Y
Employed: ❒ N ❒ Y	……	H/HELP❒ N ❒ Y
Pensioner ❒ N ❒ Y		OTHER ❒ N ❒ Y

Specify……..

Transport Arrangements:
(detail*)*……..

Outcomes research

- **Outcomes goals:** subject & / or significant others

"what do you wish to achieve from Pulmonary Rehab ?"

……
……
……

What did you like about the CDSMP?
What didn't you like?
Which order do you think people should do the programs (CDSMP/PRP orPRP/CDSMP) and why?

Appendix 10

The St. George's Hospital Respiratory Questionnaire (SGRQ)

This questionnaire is designed to help us learn much more about your breathing is troubling you. We want to find out which aspects of your illness cause you most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the rest of the questionnaire, please tick one box to show how you would describe your present health.

Very good	Good	Fair	Poor	Very Poor
☐	☐	☐	☐	☐

PART 1

These questions are about how much chest trouble you have had over the last 3 months. Please circle the response which best describes you.

	Most days a Week	Several days a week	A few days a month	Only with chest infections	Not at all
1. Over the last 3 months, I have coughed:	1	2	3	4	5
2. Over the last 3 months, I have brought up phlegm (sputum)	1	2	3	4	5
3. Over the last 3 months, I have had shortness of breath:	1	2	3	4	5
4. Over the last 3 months, I have had attacks of wheezing	1	2	3	4	5
5. During the past 3 months, how many severe chest attacks have you had?	more than 3 attacks	3 attacks	2 attacks	1 attacks	No attacks
6. How long did the worst attack of chest trouble last? (Go to Q.7 if you had no severe attacks)	A week or more	3 or more days	1 or 2 days	less than a day	
7. Over the last 3 months, in an average week how many good days (with little chest trouble) have you had?	No good days	1 or 2 good days	3 or 4 good days	Nearly every day is good	Every day is good
8. If you have a wheeze, is it worse in the morning ?	No	Yes			

PART 2

Section 1 How would you describe your chest condition?
Please tick only 1 box
The most important problem I have. Causes me quite a lot of problems. Causes me a few problems

☐ ☐ ☐

If you have ever had paid employment, please tick one of these boxes:

My chest trouble made me stop. work altogether	My chest trouble interferes with my Work or made me change my work	My chest trouble does not affect my work
☐	☐	☐

Section 2 These questions are about what activities usually make you breathless these days. For each item, please tick the box for either true or false as it applies to you:

	True	False
Sitting or lying still	☐	☐
Getting washed or dressed	☐	☐
Walking around the home	☐	☐
Walking outside on level ground	☐	☐
Walking up one flight of stairs	☐	☐
Walking up hills	☐	☐
Playing sports or active games	☐	☐

Section 3 These are some more questions about your cough and breathlessness these days. For each item, please tick the box for either true or false as it applies to you.

	True	False
My cough hurts	☐	☐
My cough makes me tired	☐	☐
I am breathless when I talk	☐	☐
I am breathless when I bend over	☐	☐
My cough or breathing disturbs my sleep	☐	☐
I get exhausted easily	☐	☐

PART 2

Section 1 How would you describe your chest condition?
Please tick only 1 box
The most important problem I have. Causes me quite a lot of problems. Causes me a few problems

☐ ☐ ☐

If you have ever had paid employment, please tick one of these boxes:

My chest trouble made me stop. work altogether	My chest trouble interferes with my Work or made me change my work	My chest trouble does not affect my work
☐	☐	☐

Section 2 These questions are about what activities usually make you breathless these days. For each item, please tick the box for either true or false as it applies to you:

	True	False
Sitting or lying still	☐	☐
Getting washed or dressed	☐	☐
Walking around the home	☐	☐
Walking outside on level ground	☐	☐
Walking up one flight of stairs	☐	☐
Walking up hills	☐	☐
Playing sports or active games	☐	☐

Section 3 These are some more questions about your cough and breathlessness these days. For each item, please tick the box for either true or false as it applies to you.

	True	False
My cough hurts	☐	☐
My cough makes me tired	☐	☐
I am breathless when I talk	☐	☐
I am breathless when I bend over	☐	☐
My cough or breathing disturbs my sleep	☐	☐
I get exhausted easily	☐	☐

Section 6 *These are questions about how your activities might be affected by your breathing.*
For each question, please tick true if one or more of the parts of the question apply to you because of your breathing.
Otherwise tick false.

	True	False
I take a long time to get washed or dressed	☐	☐
I cannot take a bath or shower, or I take a long time	☐	☐
I walk slower than other people, or I stop for rests	☐	☐
Jobs such as housework take a long time, or I have to stop for rests	☐	☐
If I walk up one flight of stairs, I have to go slowly or stop	☐	☐
If I hurry or walk fast, I have to stop or slow down.	☐	☐
My breathing makes it difficult to do things such as Walk up hills, carry things up stairs, light gardening E.g. weeding, dance, play bowls or play golf.	☐	☐
My breathing makes it difficult to do things such as carry heavy loads, dig the garden, jog or walk fast (8 km/hr), play tennis or swim laps.	☐	☐
My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports.	☐	☐

Section 7 We would like to know how your chest trouble usually affects your daily life. Please tick either true or false:
(Remember that true only applies to you if you cannot do something because of your breathing.)

	True	False
I cannot play sports or active games	☐	☐
I cannot go out for entertainment or recreation	☐	☐
I cannot go out of the house to do the shopping	☐	☐
I cannot do housework	☐	☐
I cannot move from my bed or my chair	☐	☐

Here is a list of other activities that your chest trouble may prevent you from doing.
(You do not have to tick these they are just to remind you of ways in which your breathlessness may affect you.)

- **Going for walks or walking the dog**
- **Sexual intercourse**
- **Going out to church, or place of entertainment**
- **Going out in bad weather or into smoky rooms**
- **Visiting family or friends or playing with children**

Please write in any other important activities that your chest trouble may stop you doing:

_____

_____

Now, would you tick one box (one only) which you think best describes how your chest trouble affects you:

It does not stop me from doing anything I would like to do	☐
It stops me doing one or two things I would like to do	☐
It stops me doing most of the things I would like to do	☐
It stops me doing everything I would like to do	☐

Thank you for completing this questionnaire

Appendix 11

ASSESSMENT OF QUALITY OF LIFE

INSTRUCTIONS:

*This questionnaire has 15 questions and will take about 10 minutes. The questions are about your health **during the last week**. Please circle the answer that best describes you.*

ILLNESS

1 Concerning your use of prescribed medicines in the last week

Would you say that:

A. I do not or rarely use any medicines at all
B. I use one or two medicines regularly.
C. I needed to use three or four medicinal drugs regularly
D. I use five or more medicinal drugs regularly.

2 To what extent do I rely on a medical aid? (NOT glasses or hearing aid)

For example: walking frame, wheelchair, prothesis etc.

A. I do not use any medicines and/or medical aids.
B. I occasionally use medicines or/or medicinal aids.
C. I regularly use medicinal and/or medical aids.
D. I have to constantly take medicines or use a medical aid.

3 Do I need regular medical treatment from a doctor or other Health professional?

A. I do not need regular medical treatment.
B. Although I have some regular medical treatment, I am not dependent on this.
C. I am dependent on having regular medical treatment.
D. My life is dependent upon regular medical treatment.

INDEPENDENT LIVING

4 Do I need help looking after myself?

This question refers to personal grooming, going to the bathroom, dressing

A. I need no help at all.
B Occasionally I need some help with personal care tasks.
C. I need help with the more difficult personal care tasks.
D. I need daily help with most or all personal care tasks.

5 When doing household tasks:

For example: preparing food, gardening, using the video recorder, telephone, Or washing the car

A. I need no help at all.
B. Occasionally I need some help with household tasks.
C. I need help with more difficult household tasks.
D. I need daily help with most or all household tasks.

6 Thinking about how easily I get around my home and the community:

A. I get around my home & the community by myself without any difficulty.
B. I find it difficult to get around my home & community by myself.
C. I cannot get around the community by myself, but I can get around my home with some difficulty.
D. I cannot get around either the community or my home by myself.

SOCIAL RELATIONSHIPS

7. Because of my health, the relationships I have with other people generally:

A. Are very close and warm
B. Are sometimes close and warm
C. Are seldom close and warm
D. I have no close and warm relationships

8. Thinking about my relationship with other people:

A. I have plenty of friends am never lonely.
B. Although I have friends, I am occasionally lonely.
C. I have some friends, but am often lonely for company.
D. I am socially isolated and feel lonely.

9. Thinking about my health and my family:

A. My role in the family is unaffected by my health.
B. There are some parts of my family role I cannot carry out.
C. There are many parts of my family role I cannot carryout.
D. I cannot carry out any part of my family role.

PHYSICAL SENSES

10. Thinking about my eyesight, including when using my glasses or contact lenses:

A. I can see normally
B. I have some difficulty focusing on things, or I do not see them sharply. *For example: small print, a newspaper, or seeing objects at a distance.*
C. I have a lot of difficulty seeing things. My vision is blurred. *For example: I can see just enough to get by with.*
D. I only see general shapes, or am blind. *For example: I need a guide to move around.*

11. Thinking about my hearing in the last week, including use of a hearing aid if needed:

A. I hear normally.
B. I have some difficulty hearing or I do not hear clearly. *For example: I ask people to speak up, or turn up the TV or radio volume.*
C. I have difficulty hearing things clearly. *For example: Often I do not understand what is being said. I usually do not take part in conversations because I cannot hear what is said.*
D. I hear very little indeed. *For example: I cannot fully understand loud voices speaking directly to me.*

12. When I communicate with others:

For example: by talking, listening, writing or signing

A. I have no trouble speaking to them or understanding what they are saying.
B. I have some difficulty being understood by people who do not know me. I have no trouble understanding what others are saying to me.
C. I am only understood by people who know me well. I have great trouble understanding what others are saying to me.
D. I cannot adequately communicate with others.

PSYCHOLOGICAL WELL BEING

13. If I think about how I have slept in the last week:

A. I am able to sleep without difficulty most of the time.

B. My sleep is interrupted some of the time, but I am usually able to go back to sleep without difficulty.

C. My sleep is interrupted most nights, but I am usually able to back to sleep without difficulty.

D. I sleep in short bursts only. I am awake most of the night.

14. Thinking about how I generally feel:

A. I do not feel anxious, worried or depressed.
B. I am slightly anxious, worried or depressed.
C. I feel moderately anxious, worried or depressed.
D. I am extremely anxious, worried or depressed.

15. How much pain or discomfort do I experience?

A. None at all
B. . I have moderate pain
C. I suffer from severe pain
D. I suffer from unbearable pain.

Thank you for completing this questionnaire.

Appendix 12

Please read each question to determine how **confident** you are that you could manage in that situation.

1. **If something looks too complicated I will not even bother to try it.**

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

2. I avoid trying to learn new things when they look too difficult.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

3.**When trying to learn something new, I soon give up if I am not successful.**

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

4. When I make plans I am certain I can make them work.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

5. **If I can't do the job the first time, I keep trying until I can.**

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

6.When I have something unpleasant to do, I stick to it until I finish it.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

7.When I decide to do something, I go right to work on it.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

Please Turn Over…….

8. Failure just makes me try harder.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

9.When I set important goals for myself, I rarely achieve them.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

10.I do not seem capable of dealing with most problems that come up in my life.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

11. When unexpected problems occur, I don't handle them very well.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

12. I feel insecure about my ability to do things.

□Strongly disagree □Disagree □Neither Agree or Disagree □Agree □Strongly agree

Thank you for completing this questionnaire.

GSES-12

Appendix 13 Comparison of Baseline characteristics of Hospital A and B

	Hospital A		Hospital B		**P value**
Subjects	N= 97		N= 23		
Subjects (male)	50 (52%)		15(63%)		0.43
Australian Born	64 (66%)		16 (67%)		0.89
COPD Severity[A]					0.32
Mild	3 (3%)		1 (4%)		
Moderate IIA	27 (28%)		3 (13%)		
Moderate IIB	35 (36%)		9 (37%)		
Severe	29 (30%)		11 (46%)		
Long Term Oxygen Therapy ($LT0_2$)	18 (19%)		4 (17%)		0.59
Never Smoked	7 (7%)		0 (0%)		<0.002*
Current Smokers	13 (13%)		0 (0%)		<0.0001*
Former Smokers	77 (80%)		23 (100%)		<0.0001*
	M	**SD**	**M**	**SD**	
($LT0_2$)Hours per day	14	7.4	18	7.1	
($LT0_2$) *Litres(l)* per minute	2.6	0.9	2.0	0.7	
FEV_1 *l* Actual	1.01	0.53	0.88	0.46	0.24
FEV_1 *l*% Predicted	42	20	36	16	0.14
FVC *l* Actual	2.32	0.77	1.63	0.68	<0.0001*
FVC *l*% Predicted	74	18	52	15	<0.0001*
Smoking History Pack Years	40	26	51	20	0.06
Age (years)	68.3	9.2	70.3	6.9	0.31
Co-Morbidities	1.7	1.2	2.3	1.4	0.10
Body Mass Index	27.2	6.1	25	14	

Note [A] GOLD classification *statistically significant at P<0.05 N/A not available

Appendix 14: Summary of the baseline characteristics of the participants who did not complete the six - week intervention or control period

Participant ID.	Age (years)	Gender	Smoker /resumed	Body Mass Index	No. co-morbidities	COPD (GOLD) classification
CDSMP GROUP						
25	65	M	No	29	0	2
37	67	M	Yes	24	0	2
92	64	F	No	29	3	2
PRP GROUP						
3	69	M	Yes	32	1	1
6	59	F	Yes	28	0	2
21	43	M	Yes	44	2	2
30	63	M	No	31	0	2
34	78	M	No	39	2	2
35	61	F	No	21	1	3
50	72	M	No	23	1	3
51	73	F	No	23	0	3
63	65	M	Yes	27	0	2
66	56	M	Yes	43	4	2
76	72	F	No	21	3	3
CONTROL GROUP						
105	78	M	No	N/A	5	3
112	80	F	No	N/A	1	2

Note : N/A Not Available

Appendix 15 Baseline and week seven MRC Dyspnoea by allocated group

Group		N	Grade				
			1	2	3	4	5
CDSMP	Baseline	**26**	0	7	12	6	1
	Week 7	**26**	0	10	9	5	2
PRP	Baseline	**56**	0	15	29	13	0
	Week 7	**56**	5	26	17	9	0
CONTROL	Baseline	**23**	0	3	12	8	0
	Week 7	**23**	Not Measured				

Appendix 16 Summary results of the SGRQ within groups

Measure		CDSMP				PRP				CONTROL			
		Mean(SD)	**t**	**P**	***n***	**Mean (SD)**	**t**	**P**	***n***	**Mean (SD)**	**t**	**P**	***n***
Symptoms	Baseline Week 7	58.89(25.42) 55.52(22.06)	*.76*	0.46	*27*	55.76 (21.71) 48.45(22.81)	3.05	*.003*	56	56.59 (27.96) 56.54(24.19)	*-.62*	.95	22
Activities	Baseline Week 7	73.16(15.49) 68.04(21.71)	*2.09*	0.047		72.26 (16.48) 67.48(19.13*)*	2.61	*.01*		71.55 (19.25) 64.25(26.57)	*.71*	.49	
Impacts	Baseline Week 7	43.31(15.99) 37.27(18.05)	*2.17*	0.04		35.79 (16.74) 31.48(19.13)	2.43	*.02*		36.25 (20.21) 36.94(23.53)	*.09*	.93	
∑ Score	Baseline Week 7	54.95(14.38) 49.63(16.83)	*2.69*	0.01		50.17 (15.09) 45.20(15.45)	3.53	*.001*		50.48 (18.63) 48.44 (22.53)	*.34*	.74	

Appendix 17 Summary results of the Assessment of Quality of Life

			CDSMP		**PRP**		**CONTROL**	**Value**	
Measure		*n*	*M (SD)*	*n*	*M (SD)*	*n*	*M (SD)*	F	P
Illness	Baseline	*24*	5.36 (2.22)	*57*	5.05 (2.03	*23*	6.22 (1.93)	2.63	0.08
	Week 7	*24*	7.71 (2.11))	*57*	5.23 (2.39)	*23*	5.69 (2.09)		
Independent Living	Baseline	*24*	2.75 (2.38)	*57*	1.68 (1.88)	*23*	1.96 (2.34)	2.23	0.11
	Week 7	*24*	1.83 (2.06)	*57*	1.28 (1.74)	*23*	2.01 (2.03)		
Physical Senses	Baseline	*24*	1.71 (2.03)	*57*	1.12 (1.34)	*23*	1.61 (1.49)	1.56	0.22
	Week 7	*24*	1.83 (1.55)	*57*	1.53 (1.65)	*23*	1.78 (1.65)		
Social Relationships	Baseline	*24*	0.79 (0.83))	*57*	0.95 (0.97)	*23*	1.35 (1.4)	1.79	0.17
	Week 7	*24*	0.96 (1.04)	*57*	1.05 (1.16)	*23*	1.30 (1.39)		
Psychological Well-being	Baseline	*24*	2.29 (1.71)	*57*	2.51 (1.66)	*23*	2.52 (1.86)	0.15	0.86
	Week 7	*24*	2.29 (1.37)	*57*	2.09 (1.64)	*23*	2.78 (2.21)		
∑ Score	Baseline	*24*	12.92 (7.04)	*57*	11.29 (4.77)	*23*	13.65 (6.09)	1.68	0.19
	Week 7	*24*	12.63 (5.09)	*57*	11.18 (5.60)	*23*	13.56 (7.09)		

Appendix 18 Two way ANOVA summary results for The AQoL

Dependent Variable: Week 7 outcomes	*df*	*MS*	*F*	η^2	**Group Mean Differences** Scheffe
Total Score					
Group Allocation	2	18.11	.68		
The AQoL total score	24	63.48	2.39**	.52	none
Group allocation*	23	18.52	.69		
The AQoL total score					
Error	54	26.58			
Subscale: illness					
Group Allocation	2	5.63	1.28		
Subscale score	8	12.49	2.84**	.22	none
Group allocation*	13	3.65	.83		
Subscale score					
Error	80	4.4			
Subscale: independent living Group					
Allocation	2	11.84	4.51*	.10	
Illness scale score	8	11.21	4.27**	.29	none
Group allocation*	13	4.22	1.61		
Subscale score					
Error	80	2.63			
Subscale: physical senses Group	2	.03	.01		
Allocation					
Subscale score	7	10.23	5.02**	.29	none
Group allocation*	9	1.36	.67		
Subscale score					
Error	85	2.04			
Subscale: social relationships					
Group Allocation	2	.46	.43		
Subscale score	4	10.60	9.91**	.30	none
Group allocation*	6	1.17	1.09		
Subscale score					
Error	91	1.07			
Subscale: psychological well - being					
Group Allocation	2	6.08	2.7		
Subscale score	7	11.94	5.30**	.31	none
Group allocation*	12	2.87	1.28		
Subscale score					
Error	82	2.25			

Note: * $p<0.05$ **$p<0.01$

Appendix 19 The group mean AQoL summary results

Allocation	Baseline Σ Score M (SD) Range	Week 7 Σ Score M (SD) Range	Value t	P	n
CDSMP	12.92 (7.04)	12.63 (5.09)	-.49	.63	24
PRP	11.29 (4.77)	11.18 (5.60)	.18	.86	57
CONTROL	13.65 (6.09)	13.56 (7.09)	.41	.69	23

Appendix 20 Summary profile of study participants who declined to attend PRP+m

Study No.	Age (years)	Gender	Smoker/ resumed	Body Mass Index	No. co-morbidities	COPD (GOLD) classification	Reason
15	88	M	NO	31	4	2	" I'm too old to exercise & its hard work"
16	83	M	NO	29	3	1	Maintain domestic harmony, spouse unhappy with increased independence
26	59	M	NO	32	3	3	"(Exercise) too much effort"
36	75	F	NO	24	2	2	Not necessary; now well
41	68	F	NO	32	2	2	Not necessary; now well
57	72	F	NO	31	2	2	"(Exercise) too much effort"
59	82	F	NO	33	3	2	" I'm too old to exercise, too much effort is needed"

Appendix 21 Summary results of the 12 month MRC Dyspnoea Grade by Group Allocation

Measure MRC Dyspnoea	n	**CDSMP** **M(SD)**	**n**	**PRP** **M(SD)**	**n**	**PRP+m** **M(SD)**	**n**	**CONTROL** **M(SD)**
Baseline	26	2.95 (.76	25	2.88 (.68	26	2.79 (.66	20	3.21 (.71
Week 7	26	2.85 (.68	25	2.39 (.72	26	2.46 (.88		---
Week 26	26	2.85 (.88	25	2.57 (.89	26	2.32 (.84		---
Week 52	26	3.05 (.95	25	2.65 (1.03	26	2.35 (.65		---

Appendix 22 Week 52 MRC dyspnoea multiple comparisons Post hoc (Scheffe) results

(I) ALLOCATION	(J) ALLOCATION	Mean Difference (I-J)	Std. Error	**P Value**
CDSMP	PRP	.32	.186	.24
	PRP + m	.47	.188	.051
PRP	CDSMP	-.32	.186	.24
	PRP + m	.15	.181	.69
PRP + m	CDSMP	-.47	.188	.051
	PRP	-.15	.181	.69

Appendix 23 Week 52 MRC Dyspnoea homogenous subsets

Scheffe

ALLOCATION	*n*	Subset	
		1	2
PRP + m	22	2.45	
PRP	23	2.61	2.61
CDSMP	20		2.93
Sig.		.708	.240

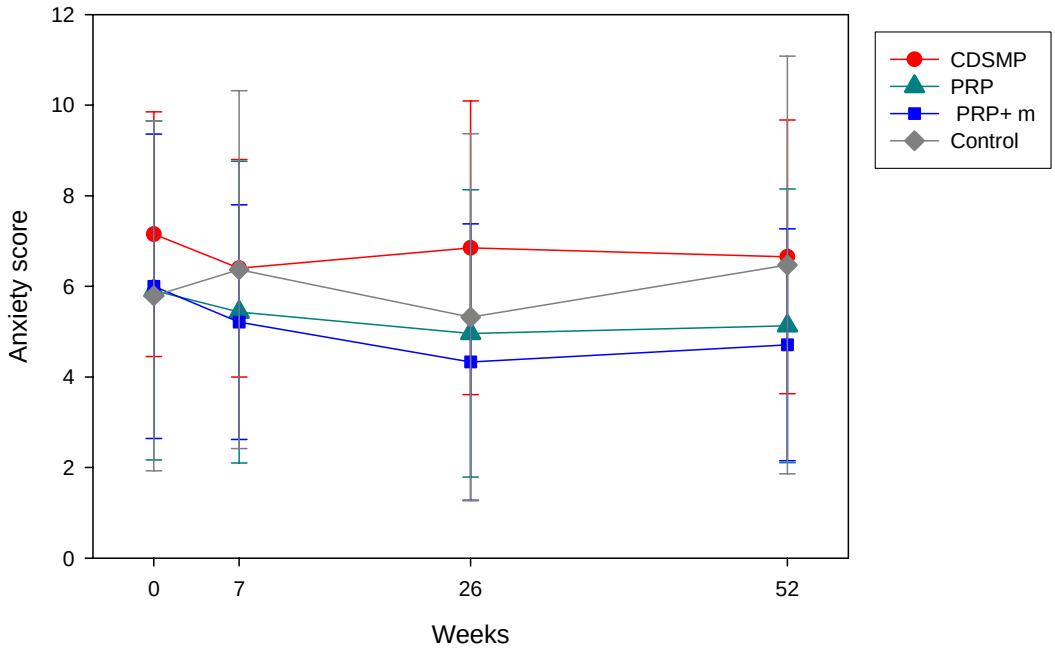
Means for groups in homogeneous subsets are displayed.
Based on Type III Sum of Squares The error term is Mean Square(Error) = .370.
a Uses Harmonic Mean Sample Size = 21.593.
b Alpha = .05.

Appendix 24 Summary results of The HAD over the 12 month period

		n	CDSMP *M(SD)*	*n*	PRP *M(SD)*	*n*	PRP+ m *M(SD)*	*n*	CONTROL *M(SD)*
Anxiety	*Baseline*	*20*	7.15(2.89	*23*	5.91(4.33	*24*	6.00 (3.97	*19*	5.79 (4.00
	Week 7	*20*	6.40 (2.56	*23*	5.43 (3.86	*24*	5.21(3.06	*19*	6.37 (4.10
	Week 26	*20*	6.58 (3.47	*23*	4.96 (3.66	*24*	4.33 (3.61	*19*	5.32 (4.20
	Week 52	*20*	6.65 (3.23	*23*	5.13 (3.49	*24*	4.71(3.03	*19*	6.47 (4.79
Depression	*Baseline*	*20*	6.15 (3.36	*23*	4.74(2.93	*24*	3.79(3.01	*19*	4.21(2.66
	Week 7	*20*	5.00 (2.47	*23*	4.22(2.98	*24*	3.67(2.93	*19*	4.55(2.65
	Week 26	*20*	5.35 (3.23	*23*	4.48(2.15	*24*	3.08(2.47	*19*	3.42(2.76
	Week 52	*20*	4.10 (2.34	*23*	4.09(2.15	*24*	2.92(2.32	*19*	4.42(3.19
Σ Score	*Baseline*	*20*	13.30 (5.08	*23*	10.65 (6.57	*24*	9.79 (6.23	*19*	10.00 (5.65
	Week 7	*20*	11.40 (4.24	*23*	9.65 (6.44	*24*	8.88 (4.44	*19*	10.89 (5.89
	Week 26	*20*	12.20 (5.56	*23*	9.43 (0.05	*24*	7.42 (5.29	*19*	8.74 (6.34
	Week 52	*20*	10.75 (4.51	*23*	9.22 (4.99	*24*	7.63 (3.89	*19*	10.89 (7.06

Appendix 25 The HAD subscale: Anxiety

A mixed ANOVA reported no effect over time, $F(2.69,220.76)=2.21$, $p = .09$, no significant interaction by group $F(8.08, 220.76)=.87$, $p=.55$ And group allocation was not a significant determinant $F(3,82)=1.22$, $p=.31$. The mean group results in the subscale Anxiety as illustrated below:



12 month follow up of Anxiety as measured with The HAD

Appendix 26 Summary results of the 12 month SGRQ by Group Allocation

	CDSMP		PRP		PRP+m		CONTROL	
	M	SD	M	SD	M	SD	M	SD
Σ SCORE								
Baseline	54.25	12.71	49.29	12.66	47.41	16.79	51.19	19.13
Week 7	47.94	16.12	44.20	15.38	40.44	15.22	51.31	21.42
Week 26	49.84	12.88	44.74	17.58	39.03	15.34	43.11	23.84
Week 52	49.65	13.79	45.24	15.68	41.89	14.68	52.68	20.61
SYMPTOMS								
Baseline	59.39	21.98	53.53	19.01	55.12	23.85	57.46	26.36
Week 7	54.09	20.84	48.23	14.95	43.90	26.01	58.82	22.51
Week 26	58.75	16.62	45.31	21.53	49.36	21.67	50.12	30.76
Week 52	59.85	17.70	50.19	20.28	51.23	22.79	62.18	22.93
ACTIVITIES								
Baseline	71.56	15.21	72.46	12.22	68.55	20.41	70.28	20.89
Week 7	66.73	19.41	65.27	16.30	61.90	21.53	66.89	24.55
Week 26	68.69	18.73	62.34	19.76	59.20	21.88	60.41	28.11
Week 52	69.26	17.69	64.72	17.24	60.99	17.97	67.83	21.29
IMPACTS								
Baseline	42.74	15.77	34.72	15.91	32.92	17.36	37.96	20.52
Week 7	35.28	17.82	30.92	19.77	27.10	14.28	40.05	23.59
Week 26	36.29	14.69	30.74	19.84	24.26	14.61	31.04	21.57
Week 52	35.26	15.56	32.56	17.91	28.05	15.04	41.07	23.50

Appendix 27 Summary results of the 12 month SGRQ by Group Allocation

GENDER = FEMALE, ALLOCATION = LORIG

Descriptive Statistics(a)

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	13	62.0846	22.58934
BLINE ACTIVITIES	13	75.1385	16.59184
BLINE IMPACTS	13	42.5385	15.94049
BLINE TOTAL	13	55.6692	14.78971
7 SYMPTOMS	13	52.9154	21.49104
7 ACTIVITIES	13	71.4538	19.64818
7 INITIAITVE	13	35.1615	16.75418
7 TOTAL	13	49.1154	15.96052
26 SYMP	11	53.1545	12.71451
26 ACTIVITIES	11	67.4545	19.77080
26 IMPACTS	11	35.5364	16.84911
26 TOTAL	11	48.1364	13.64634
52 SYMPTOMS	10	64.2566	17.62158
52 ACTIVITIES	10	71.3613	19.97638
52 IMPACTS	10	33.4380	18.92197
52 TOTAL	10	50.0496	16.30874
Valid N (listwise)	10		

GENDER = FEMALE, ALLOCATION = PRP

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	12	49.3000	23.25382
BLINE ACTIVITIES	12	69.7583	11.94224
BLINE IMPACTS	12	29.7500	15.93370
BLINE TOTAL	12	45.1250	12.22629
7 SYMPTOMS	12	48.4083	15.79099
7 ACTIVITIES	12	64.8000	17.80562
7 INITIAITVE	12	25.7417	16.61497
7 TOTAL	12	41.3333	14.71087
26 SYMP	11	35.8727	20.11532
26 ACTIVITIES	11	55.5182	22.18909
26 IMPACTS	11	21.8091	18.79758
26 TOTAL	11	34.3636	16.06202
52 SYMPTOMS	11	41.5918	20.43983
52 ACTIVITIES	11	55.7477	18.26344
52 IMPACTS	11	26.8924	17.14386
52 TOTAL	11	38.0789	15.35572
Valid N (listwise)	11		

GENDER = FEMALE, ALLOCATION = control

Descriptive Statistics(a)

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	8	57.6813	19.02774
BLINE ACTIVITIES	8	69.2150	22.98594
BLINE IMPACTS	8	38.1163	20.48163
BLINE TOTAL	8	50.7913	19.46258
7 SYMPTOMS	8	54.6813	15.08173
7 ACTIVITIES	8	63.1787	26.83296
7 INITIAITVE	8	37.8463	26.53124
7 TOTAL	8	48.3200	23.52106
26 SYMP	8	30.9825	31.54216
26 ACTIVITIES	8	40.8538	36.40418
26 IMPACTS	8	19.9450	21.83947
26 TOTAL	8	28.1150	27.11746
52 SYMPTOMS	8	39.8300	32.67788
52 ACTIVITIES	8	46.9788	36.50435
52 IMPACTS	8	29.8138	28.84284
52 TOTAL	8	36.6813	30.62027
Valid N (listwise)	8		

a GENDER = FEMALE, ALLOCATION = control

GENDER = FEMALE, ALLOCATION = prp+m

Descriptive Statistics(a)

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	17	52.2294	22.91091
BLINE ACTIVITIES	17	67.4294	22.45709
BLINE IMPACTS	17	31.3471	18.04865
BLINE TOTAL	17	45.7588	17.78212
7 SYMPTOMS	17	38.8000	23.54644
7 ACTIVITIES	17	61.5118	22.12145
7 INITIAITVE	17	24.1059	12.64345
7 TOTAL	17	37.8824	13.51921
26 SYMP	16	47.5375	23.04855
26 ACTIVITIES	16	61.4563	23.90052
26 IMPACTS	16	24.1687	16.13529
26 TOTAL	16	39.3625	17.35415
52 SYMPTOMS	15	46.5761	21.85261
52 ACTIVITIES	15	57.5354	19.17674
52 IMPACTS	15	23.6900	12.94409
52 TOTAL	15	37.7484	13.27065
Valid N (listwise)	15		

a GENDER = FEMALE, ALLOCATION = prpm

GENDER = MALE, ALLOCATION = LORIG

Descriptive Statistics(a)

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	13	55.7000	28.52289
BLINE ACTIVITIES	13	71.1846	14.69880
BLINE IMPACTS	13	44.1000	16.65038
BLINE TOTAL	13	54.2308	14.51943
7 SYMPTOMS	13	58.1308	23.18068
7 ACTIVITIES	13	64.6308	23.88816
7 INITIAITVE	13	39.3846	19.70659
7 TOTAL	13	50.1462	18.30153
26 SYMP	10	64.6700	18.07958
26 ACTIVITIES	10	71.2300	17.69244
26 IMPACTS	10	37.9800	12.02172
26 TOTAL	10	52.5000	11.78096
52 SYMPTOMS	10	55.4506	17.55632
52 ACTIVITIES	10	67.1549	15.88857
52 IMPACTS	10	37.0899	12.87140
52 TOTAL	10	49.2510	11.63046
Valid N (listwise)	10		

a GENDER = MALE, ALLOCATION = LORIG

GENDER = MALE, ALLOCATION = PRP

Descriptive Statistics(a)

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	16	60.0938	13.68013
BLINE ACTIVITIES	16	76.4438	10.62199
BLINE IMPACTS	16	41.7125	14.54977
BLINE TOTAL	16	55.2938	11.39927
7 SYMPTOMS	16	51.5438	20.34938
7 ACTIVITIES	16	70.6250	15.72622
7 INITIAITVE	16	38.8062	19.43637
7 TOTAL	16	50.5688	14.86650
26 SYMP	14	56.8357	20.39210
26 ACTIVITIES	14	69.2429	14.46623
26 IMPACTS	14	39.3214	18.14773
26 TOTAL	14	51.3000	15.59329
52 SYMPTOMS	14	59.0404	16.17855
52 ACTIVITIES	14	74.8437	11.80171
52 IMPACTS	14	37.4455	16.34225
52 TOTAL	14	52.3663	12.40992
Valid N (listwise)	13		

GENDER = MALE, ALLOCATION = control

Descriptive Statistics(a)

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	14	59.4936	28.67468
BLINE ACTIVITIES	14	70.6307	20.86218
BLINE IMPACTS	14	39.4271	22.14399
BLINE TOTAL	14	52.4807	19.94245
7 SYMPTOMS	14	61.6343	24.33491
7 ACTIVITIES	14	69.4536	21.44122
7 INITIAITVE	14	39.0529	21.16102
7 TOTAL	14	52.0164	19.15482
26 SYMP	14	50.3100	33.58952
26 ACTIVITIES	14	58.6429	31.37935
26 IMPACTS	14	30.7300	23.10452
26 TOTAL	14	42.4407	26.09048
52 SYMPTOMS	14	61.6271	27.15710
52 ACTIVITIES	14	65.2036	26.39342
52 IMPACTS	14	38.6971	24.94079
52 TOTAL	14	50.5386	23.68791
Valid N (listwise)	14		

a GENDER = MALE, ALLOCATION = control

GENDER = MALE, ALLOCATION = prp+m

Descriptive Statistics(a)

	N	Mean	Std. Deviation
BASELINE SYMPTOMS	11	61.9636	27.09761
BLINE ACTIVITIES	11	76.3909	16.33490
BLINE IMPACTS	11	40.6455	16.22469
BLINE TOTAL	11	55.0182	16.03283
7 SYMPTOMS	11	58.9182	28.02288
7 ACTIVITIES	11	75.0636	19.03987
7 INITIAITVE	11	38.4545	12.71199
7 TOTAL	11	52.9636	15.14201
26 SYMP	10	59.9300	25.96297
26 ACTIVITIES	10	61.3800	26.79137
26 IMPACTS	10	30.9800	19.77208
26 TOTAL	10	45.0000	20.82104
52 SYMPTOMS	8	62.1340	21.53687
52 ACTIVITIES	8	68.9149	12.42558
52 IMPACTS	8	37.4799	14.68897
52 TOTAL	8	51.1014	13.42705
Valid N (listwise)	7		

a GENDER = MALE, ALLOCATION = prpm

General Linear Model

Within-Subjects Factors

Measure: MEASURE_1

factor1	Dependent Variable
1	sgrqs52
2	sgrqa52
3	sgrqi52
4	sgrqt52

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	FEMALE	64.2566	17.62158	10
	Total	64.2566	17.62158	10
52 ACTIVITIES	FEMALE	71.3613	19.97638	10
	Total	71.3613	19.97638	10
52 IMPACTS	FEMALE	33.4380	18.92197	10
	Total	33.4380	18.92197	10
52 TOTAL	FEMALE	50.0496	16.30874	10
	Total	50.0496	16.30874	10

a GENDER = FEMALE, ALLOCATION = LORIG

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.815	17.566(a)	2.000	8.000	.001
	Wilks' Lambda	.185	17.566(a)	2.000	8.000	.001
	Hotelling's Trace	4.391	17.566(a)	2.000	8.000	.001
	Roy's Largest Root	4.391	17.566(a)	2.000	8.000	.001
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	8.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	7.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	8.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	7.000	1.000

a Exact statistic

b Design: Intercept+group+gender Within Subjects Design: factor1

c GENDER = FEMALE, ALLOCATION = LORIG

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	FEMALE	41.5918	20.43983	11
	Total	41.5918	20.43983	11
52 ACTIVITIES	FEMALE	55.7477	18.26344	11
	Total	55.7477	18.26344	11
52 IMPACTS	FEMALE	26.8924	17.14386	11
	Total	26.8924	17.14386	11
52 TOTAL	FEMALE	38.0789	15.35572	11
	Total	38.0789	15.35572	11

a GENDER = FEMALE, ALLOCATION = PRP

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	9.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	8.000	1.000
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	9.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	8.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	9.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	8.000	1.000

a Exact statistic
b Design: Intercept+group+gender Within Subjects Design: factor1
c GENDER = FEMALE, ALLOCATION = PRP

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	FEMALE	39.8300	32.67788	8
	Total	39.8300	32.67788	8
52 ACTIVITIES	FEMALE	46.9788	36.50435	8
	Total	46.9788	36.50435	8
52 IMPACTS	FEMALE	29.8138	28.84284	8
	Total	29.8138	28.84284	8
52 TOTAL	FEMALE	36.6813	30.62027	8
	Total	36.6813	30.62027	8

a GENDER = FEMALE, ALLOCATION = control

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	6.000	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	3.000	4.000	1.000
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	6.000	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	3.000	4.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	6.000	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	3.000	4.000	1.000

a Exact statistic
b Design: Intercept+group+gender Within Subjects Design: factor1
c GENDER = FEMALE, ALLOCATION = control

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	FEMALE	46.5761	21.85261	15
	Total	46.5761	21.85261	15
52 ACTIVITIES	FEMALE	57.5354	19.17674	15
	Total	57.5354	19.17674	15
52 IMPACTS	FEMALE	23.6900	12.94409	15
	Total	23.6900	12.94409	15
52 TOTAL	FEMALE	37.7484	13.27065	15
	Total	37.7484	13.27065	15

a GENDER = FEMALE, ALLOCATION = prpm

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	13.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	12.000	1.000
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	13.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	12.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	13.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	12.000	1.000

a Exact statistic b Design: Intercept+group+gender Within Subjects Design: factor1c GENDER = FEMALE, ALLOCATION = prpm

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	MALE	55.4506	17.55632	10
	Total	55.4506	17.55632	10
52 ACTIVITIES	MALE	67.1549	15.88857	10
	Total	67.1549	15.88857	10
52 IMPACTS	MALE	37.0899	12.87140	10
	Total	37.0899	12.87140	10
52 TOTAL	MALE	49.2510	11.63046	10
	Total	49.2510	11.63046	10

a GENDER = MALE, ALLOCATION = LORIG

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.880	29.286(a)	2.000	8.000	.000
	Wilks' Lambda	.120	29.286(a)	2.000	8.000	.000
	Hotelling's Trace	7.321	29.286(a)	2.000	8.000	.000
	Roy's Largest Root	7.321	29.286(a)	2.000	8.000	.000
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	8.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	7.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	8.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	7.000	1.000

a Exact statistic
b Design: Intercept+group+gender Within Subjects Design: factor1
c GENDER = MALE, ALLOCATION = LORIG

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	MALE	59.0404	16.17855	14
	Total	59.0404	16.17855	14
52 ACTIVITIES	MALE	74.8437	11.80171	14
	Total	74.8437	11.80171	14
52 IMPACTS	MALE	37.4455	16.34225	14
	Total	37.4455	16.34225	14
52 TOTAL	MALE	52.3663	12.40992	14
	Total	52.3663	12.40992	14

a GENDER = MALE, ALLOCATION = PRP

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	12.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	11.000	1.000
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	12.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	11.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	12.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	11.000	1.000

a Exact statisticb Design: Intercept+group+gender Within Subjects Design: factor1
c GENDER = MALE, ALLOCATION = PRP

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	MALE	61.6271	27.15710	14
	Total	61.6271	27.15710	14
52 ACTIVITIES	MALE	65.2036	26.39342	14
	Total	65.2036	26.39342	14
52 IMPACTS	MALE	38.6971	24.94079	14
	Total	38.6971	24.94079	14
52 TOTAL	MALE	50.5386	23.68791	14
	Total	50.5386	23.68791	14

a GENDER = MALE, ALLOCATION = control

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	12.000	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	3.000	10.000	1.000
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	12.000	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	3.000	10.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	12.000	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	3.000	10.000	1.000

a Exact statisticb Design: Intercept+group+gender Within Subjects Design: factor1
c GENDER = MALE, ALLOCATION = control

Descriptive Statistics(a)

	GENDER	Mean	Std. Deviation	N
52 SYMPTOMS	MALE	62.1340	21.53687	8
	Total	62.1340	21.53687	8
52 ACTIVITIES	MALE	68.9149	12.42558	8
	Total	68.9149	12.42558	8
52 IMPACTS	MALE	37.4799	14.68897	8
	Total	37.4799	14.68897	8
52 TOTAL	MALE	51.1014	13.42705	8
	Total	51.1014	13.42705	8

a GENDER = MALE, ALLOCATION = prpm

Multivariate Tests(b,c)

Effect		Value	F	Hypothesis df	Error df	Sig.
factor1	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	6.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	5.000	1.000
factor1 * group	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	6.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	5.000	1.000
factor1 * gender	Pillai's Trace	.000	.(a)	.000	.000	.
	Wilks' Lambda	1.000	.(a)	.000	6.500	.
	Hotelling's Trace	.000	.(a)	.000	2.000	.
	Roy's Largest Root	.000	.000(a)	2.000	5.000	1.000

a Exact statistic
b Design: Intercept+group+gender Within Subjects Design: factor1
c GENDER = MALE, ALLOCATION = prpm

Appendix 28 Summary results of the GSES with 12 month follow up

			CDSMP		PRP		PRP+ m
		n	***M(SD)***	***n***	***M(SD)***	***n***	***M(SD)***
Persistence	*Baseline*	19	18.74(3.12	20	18.15 (4.13	22	18.82(3.55
	Week 7	*19*	15.53 (2.32	20	15.00(3.03	*22*	13.86(3.12
	Week 26	*19*	15.11(2.05	20	15.30 (2.77	*22*	14.50(2.94
	Week 52	*19*	14.23 (2.73	20	14.25(2.61	*22*	13.18(4.35
Initiative	*Baseline*	*19*	10.95(2.15	20	10.90(2.19	*22*	10.95(1.86
	Week 7	*19*	11.58(1.77	20	11.90(1.80	*22*	11.50(2.16
	Week 26	*19*	10.63(1.49	20	11.80(1.44	*22*	10.95(1.62
	Week 52	*19*	10.74(1.82	20	11.15(1.76	*22*	10.41(3.32
Effort	*Baseline*	*19*	14.11(2.36	20	14.10(3.28	*22*	14.82(3.07
	Week 7	*19*	19.84(2.95	20	19.80(2.95	*22*	19.36(3.14
	Week 26	*19*	19.68(2.61	20	19.50(3.25	*22*	19.09(3.31
	Week 52	*19*	18.89(3.07	20	18.15(2.83	*22*	17.36(5.85

Appendix 29 Collective weekly functional activity by gender

No intervention group incrementally increased their functional activity over the six-week period. An examination of the results by gender does not indicate that either intervention group behaved differently.