Coventry University

DOCTOR OF PHILOSOPHY

The effectiveness of a Self-management Programme of Activity Coping and Education - SPACE for COPD - in Primary Care

Mitchell, Katy

Award date:
2013

Awarding institution:
Coventry University

Link to publication

General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of this thesis for personal non-commercial research or study
- This thesis cannot be reproduced or quoted extensively from without first obtaining permission from the copyright holder(s)
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

Take down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Download date: 24. May. 2021

The Effectiveness of a Self-management Programme of Activity Coping and Education - SPACE FOR COPD - in Primary Care

By

Katy Mitchell MCSP

A thesis submitted in partial fulfilment of the University's requirements for the Degree of Doctor of Philosophy (PhD).

In collaboration with:

The Pulmonary Rehabilitation and Research Group,

Glenfield Hospital, Groby Road, Leicester, LE3 9QP

Submitted to Coventry University May 2013

Declaration

The work submitted within this thesis has been undertaken during the period of my registration. I declare that this work is my own, conducted by myself with assistance where acknowledged. Assistance with recruitment was received from Jane Robertson at the Primary Care Respiratory Network (PCRN), Vicki Warrington conducted blinded follow-up assessments and statistical support was received from Dr. John Bankart

No part of this thesis has been submitted in a previous application for a higher degree.

Signature

Date:

Acknowledgements

The submission of this work would not have been possible without the support and assistance of many people, to whom I owe my gratitude and thanks.

Firstly, I thank my supervisory team who have mentored me through this process. My director of studies, Professor Sally Singh, I thank for giving me the opportunity and encouraging me to commence my PhD. She has provided me with an admirable role model for hard work and striving for excellence. The exciting career opportunities I have had over the past few years I owe to her. I thank Dr. Louise Sewell whose encouraging words have instilled in me self-belief when at times it has seemed impossible. Her common sense and sage advice has helped me to stay focused, and her attention to detail has been critical to this work.

I would like to thank the people who worked on, or contributed to this research study. Many thanks to Vicki Warrington for working so hard on the data collection for this trial, John Bankart for statistical support, Jane Robertson for assistance with recruitment and Lindsay Apps for introducing me to and training me in using the SPACE manual. My thanks are further extended to all the staff at the pulmonary rehabilitation team at Glenfield Hospital for their on-going support and camaraderie.

I thank my Mum for working so hard to makes things possible for me, and encouraging me to go for it.

Finally, thank you to my husband James. Thank you for your unfailing support, your faith in me, and for keeping a smile on my face.

Abstract

Introduction: COPD is a progressive disease, characterised by symptoms of dyspnoea, fatigue, exercise intolerance and reduced physical activity, resulting in impaired quality of life. Furthermore, the disease poses a significant burden on healthcare systems around the world. SPACE FOR COPD is a new self-management programme which aims to support individuals in acquiring the knowledge and skills required to optimise their emotional and medical well-being.

Methods: This thesis describes a randomised controlled trial which aims to establish the effectiveness of a SPACE FOR COPD compared with usual care alone. 184 people with COPD were recruited from primary care. Individuals were randomly allocated to receive either the SPACE FOR COPD intervention or to continue with their usual care. The primary outcome was a measure of health-related quality of life (HRQoL), the Chronic Respiratory Questionnaire – Self Report (CRQ-SR) dyspnoea domain. Secondary measures included exercise performance, anxiety, depression, knowledge, self-efficacy and physical activity. Outcome measures were recorded at baseline, six weeks and six months.

Results: There was no significant between-group difference in the change in dyspnoea at six months, therefore our hypothesis was rejected. In secondary outcomes, there were significant gains in HRQoL, exercise, performance, anxiety, knowledge and steps at six weeks, and at six months changes in

exercise performance and anxiety remained statistically significant. Correction for multiple comparisons, however, had not been made.

Conclusions: SPACE FOR COPD did not result in improved dyspnoea, over and above usual care at six months. The programme may confer significant benefits in HRQoL, exercise performance, anxiety, knowledge and physical activity over and above usual care in the short-term, and gains in anxiety and exercise performance maintained at six months. Although these patients were relatively early within the course of their disease, physical activity was low, highlighting the need for a lifestyle intervention in this group of patients. Exploration of the potential benefit of additional on-going support, and delivery within group settings may of value in order to support the maintenance of these benefits in the medium- and longer-term.

Contents

Declaration **2**

Acknowledgements **3**

Abstract **5**

Contents **7**

Index of figures **11**

Index of tables **14**

Index of Appendices **18**

Publications **19**

Abbreviations List **20**

Chapter 1: Introduction **25**

1.1 Background 25

1.2 Aims and objectives 27

1.3 Structure and setting 28

Chapter 2: Literature Review **31**

2.1 Chronic Obstructive Pulmonary Disease 31

2.1.2 Risk factors 32

2.1.3 Pathophysiology 33

2.1.4 Clinical features 33

2.1.5 Prevalence 36

2.1.6 Disease burden 37

2.2 Physical activity 39

2.2.1 Physical activity and COPD 39

2.2.2 Measuring physical activity 41

2.3 General management of COPD 46

2.3.1 Smoking cessation 46

2.3.2 Pharmacotherapy 47

2.3.3 Pulmonary rehabilitation 48

2.4 Chronic care and self-management 51

2.4.1 Approach to management of chronic illness 51

2.4.2 The Chronic Care Model 52

2.4.3 Definition and principles of self-management 53

2.4.4 Mechanisms of self-management 57

2.4.5 Motivational Interviewing 60

2.4.6 Outcomes of self-management 62

2.4 Self-management and COPD 65

2.4.1 Current self-management strategies for COPD 65

2.5.2 Summary of self-management programmes for COPD 94

2.6 Literature summary 101

Chapter 3: Methods **104**

3.1 Introduction 104

3.2 Main study design 104

3.3 Randomisation and blinding 105

3.4 Patient recruitment details 106

3.4.1 Ethical approval 106

3.4.2 Recruitment

3.4.3 Inclusion criteria 107

3.4.4 Exclusion criteria 108

3.5 Outcome measures 108

3.6 The SPACE FOR COPD intervention 114

3.6.1 The SPACE FOR COPD manual introduction 115

3.6.2 Telephone support 118

3.7 Best usual care 119

3.8 Data storage 119

3.9 Sample size 119

3.10 Statistical analysis 120

Chapter 4: SPACE FOR COPD – results at six weeks 122

4.1 Introduction 122

4.2 Aims 123

4.3 Methods 123

4.4 Results 127

4.5 Discussion 137

Chapter 5: The effectiveness of a SPACE FOR COPD at six months 156

5.1 Introduction 156

5.2 Hypothesis and aims 157

5.3 Methods 157

5.4 Results 160

5.5 Discussion 177

Chapter 6: Physical activity in a population of patients with COPD managed in primary care 194

6.1 Introduction 194

6.2 Aims 197

6.3 Methods 197

6.4 Results 203

6.5 Discussion 214

Chapter 7: Physical activity following SPACE FOR COPD: does it change and can it be predicted? **227**

7.1 Introduction 227

7.2 Aims 228

7.3 Methods 228

7.4 Results 230

7.5 Discussion 239

Chapter 8: General discussion **249**

8.1 Main findings 249

8.1.1 The Population 252

8.1.2 The Intervention 256

8.2 Study Limitations 260

8.3 Areas for further study 266

8.4 Final conclusions 273

References **275**

Appendices **298**

Index of Figures

Figure 2.1 GOLD 2011 disease severity classification 35

Figure 2.2 COPD value pyramid 50

Figure 2.3 The Chronic Care Model 53

Figure 2.4 Self-efficacy model 58

Figure 2.5 Model of behaviour change 59

Figure 2.6 Grid of outcomes on HRQoL 95

Figure 2.7 Grid of outcomes on exercise performance 95

Figure 2.8 A Spectrum of Self-management Support 99

Figure 3.1 Study Design 105

Figure 3.2 Placement of the SenseWear Armband 114

Figure 3.3 Front cover of the SPACE FOR COPD manual 115

Figure 4.1 Study Design at six weeks 124

Figure 4.2 Mean changes in CRQ-SR scores from baseline to six weeks 132

Figure 4.3 Mean change in HADS scores from baseline to six weeks 133

Figure 4.4 Baseline and six week scores for ISWT 135

Figure 4.5 Baseline and six week scores for ESWT 136

Figure 4.6 Grid of outcomes on HRQoL (including SPACE FOR COPD) 139

Figure 5.1 CONSORT flow diagram of patient recruitment, randomisation and reason for withdrawal 161

Figure 5.2 Mean dyspnoea scores for SPACE FOR COPD 164

and usual care groups at three time points

Figure 5.3 Mean fatigue scores for SPACE FOR COPD and usual care groups at three time points 168

Figure 5.4 Mean emotion scores for SPACE FOR COPD and usual care groups at three time points 168

Figure 5.5 Mean mastery scores for SPACE FOR COPD and usual care groups at three time points 169

Figure 5.6 Mean ESWT scores for SPACE FOR COPD and usual care groups at three time points 171

Figure 5.7 Mean HADS anxiety scores at three time points for the sub-group with a baseline score more than or equal to 8 174

Figure 5.8 Mean HADS depression scores at three time points for the sub-group with a baseline score more than or equal to 8 174

Figure 6.1 Output from the SenseWear Armband during ESWT 194

Figure 6.2 Output from the SenseWear Armband 200

Figure 6.3 Advanced output from the SenseWear Armband 201

Figure 6.4 Steps across the MRC grades 206

Figure 6.5 Physical Activity Level across the MRC grades 206

Figure 6.6 Steps across the GOLD stages 208

Figure 6.7 Physical Activity Level across the GOLD stages 208

Figure 6.8 The Physical Activity Level of the population defined by thresholds of activity 209

Figure 6.9 Cumulated total time spent in various bouts over 3 METs for the whole sample (n=128) during seven days 211

Figure 6.10 Time spent above 3 METs in total and in bouts 213

of at least 10 minutes

Figure 6.11 Scatter plot of steps and time spent over 3 METs in at least 10 minute bouts 213

Figure 7.1 Time spent over 3 METs in at least 10 minute bouts at all time points for both SPACE FOR COPD and usual care groups 236

Figure 7.2 Physical Activity Level at three time points for both SPACE FOR COPD and usual care groups 236

Figure 7.3 Number of steps at all time points for SPACE FOR COPD and usual care groups 237

Figure 7.4 Boubeau's model of behaviour change 243

Figure 7.5 Model of behaviour change 245

Figure 8.1 The Transtheoretical model of change 263

Figure 8.2 Guidelines for complex interventions 267

Index of Tables

Table 2.1 GOLD classification of COPD disease severity 32

Table 2.2 Medical Research Council Dyspnoea Scale 34

Table 2.3 Average costs per person for general management and management of an acute exacerbation of COPD 39

Table 2.4 Summary of self-management studies for COPD 68

Table 4.1 Reasons for study withdrawal 127

Table 4.2 Baseline characteristics of SPACE FOR COPD and usual care groups 128

Table 4.3 Baseline characteristics of completers and non-completers at six weeks 129

Table 4.4 Between-group differences in the change in CRQ-SR from baseline to 6 weeks 130

Table 4.5 CRQ-SR at baseline, six weeks and mean change for SPACE FOR COPD and usual care groups 131

Table 4.6 Between-group differences in the change in the HADS scores 132

Table 4.7 HADS at baseline, six weeks and mean change scores for SPACE FOR COPD and usual care groups 133

Table 4.8 Between-group differences in the change in ISWT and ESWT from baseline to six weeks 134

Table 4.9 ISWT and ESWT at baseline, six-week and mean change for SPACE FOR COPD and usual care groups 135

Table 4.10 Between-group differences in the change in knowledge and self-efficacy from baseline to six weeks 136

Table 4.10 Knowledge and self-efficacy at baseline, six-week and mean change for SPACE FOR COPD and usual care groups 137

Table 5.1 Baseline characteristics and baseline outcome measures of patients who completed and did not complete the study 162

Table 5.2 Significance levels of within-subject effects of time and time and intervention and between-subject effects for the CRQ-SR dyspnoea score 163

Table 5.3 Mean baseline, six weeks, six months and change scores for the CRQ-SR dyspnoea domain 164

Table 5.4 Number of responders and non-responders in SPACE FOR COPD and usual care groups measured by the CRQ-SR dyspnoea score 165

Table 5.5 Significance levels of within-subject effects of time and time and intervention and between-subject effects for the CRQ-SR fatigue, emotion and mastery domains 166

Table 5.6 Mean baseline, six weeks, six months and change scores for CRQ-SR fatigue, emotion and mastery domains 167

Table 5.7 Significance levels of within-subject effects of time and time and intervention and between-subject effects for the ISWT and ESWT 170

Table 5.8 Mean baseline, six weeks, six months and change scores for the ISWT and ESWT 170

Table 5.9 Significance levels of within-subject effects of time and time and intervention and between-subject effects for anxiety and depression 172

Table 5.10 Mean baseline, six weeks, six months and change scores for anxiety and depression 172

Table 5.11 Mean baseline, six weeks, six months and change scores for anxiety and depression for a sub-group of participants with baseline scores more than or equal to 8 173

Table 5.12 Significance levels of within-subject effects of time and time and intervention and between-subject effects for knowledge and self-efficacy 175

Table 5.13 Mean baseline, six weeks, six months and change scores for knowledge and self-efficacy 176

Table 5.14 Healthcare utilisation for SPACE and usual care groups 177

Table 6.1 Baseline characteristics of participants included and not included in physical activity measurement 204

Table 6.2 Basic monitor variables across the MRC grades 205

Table 6.3 Basic monitor variables across the GOLD stages 207

Table 6.4 Basic monitor variables for the population at baseline 209

Table 6.5 Activity classification by three different variables 212

Table 7.1 Baseline characteristics of those included and not included in activity monitor analysis 231

Table 7.2 Baseline characteristics of SPACE FOR COPD and usual care groups 232

Table 7.3 Baseline activity monitor data of SPACE FOR COPD 233

and usual care groups included in activity monitor analysis

Table 7.4 Activity monitor output from three time points for SPACE FOR COPD and usual care groups 234

Table 7.5 Significance levels of within-subject effects of time and time and intervention and between-subject effects for activity monitor output 235

Table 7.6 Participants compliant with ACSM guidelines at three time points 238

Index of Appendices

Appendix 1 Literature Search Terms 298

Appendix 2 Editorial – Unravelling self-management: what next? 299

Appendix 3 Ethical Approval 302

Appendix 4 Patient Information Sheet 305

Appendix 5 Patient Consent Form 309

Appendix 6 Chronic Respiratory Questionnaire-Self Report 310

Appendix 7 Hospital Anxiety and Depression Scale 318

Appendix 8 Pulmonary Rehabilitation Adapted Index of Self-efficacy 319

Appendix 9 Bristol COPD Knowledge Questionnaire 320

Appendix 10 Contents page of SPACE FOR COPD manual 323

Appendix 11 Aerobic Training 324

Appendix 12 Resistance Training 325

Appendix 13 Action Plan 326

Appendix 14 Telephone contact schedule 327

Publications

Papers

Wagg, K. (2012) 'Editorial: Unravelling self-management for COPD: What next?' *Chronic Respiratory Disease* 9 (1), 5-7

Abstracts

Wagg, K., Warrington, V., Sewell, L., Bankart, J., Steiner, M., Morgan, M., and Singh, S. A self-management programme of activity coping and education (SPACE) for COPD: 6 week results from a randomised controlled trial. European Respiratory Society Congress 2012

Mitchell-Wagg, K., Warrington, V., Apps, L., Sewell, L., Bankart, J., Steiner, M., Morgan, M., Singh, S. (2012) 'S49 A Self-Management Programme of Activity Coping and Education (SPACE) For COPD: Results from a Randomised Controlled Trial'. *Thorax* 67**,** A25-A26

K.E. Mitchell, V. Warrington, L. Sewell, J. Bankart, J.E.A. Williams, M. Steiner, M. Morgan, S.J. Singh. (2013) 'A Randomised Controlled Trial Of A Self-Management Programme Of Activity Coping And Education - SPACE FOR COPD: Impact On Physical Activity At 6 Weeks'. American Thoracic Society Conference

Abbreviations

/	divided by
<	less than
≤	less than or equal to
>	more than
≥	more than or equal to
x	multiplied by
%	percent or percentage
6MWT	Six Minute Walk Test
6MWD	Six Minute Walk Distance
AE	acute exacerbation
am	ante meridian "before midday"
ANOVA	analysis of variance
ANCOVA	analysis of covariance
AOT	ambulatory oxygen therapy
ATS	American Thoracic Society
BMI	body mass index
BCKQ	Bristol COPD Knowledge Questionnaire
BMR	basal metabolic rate
BTS	British Thoracic Society
CAT	COPD Assessment Tool
cm	centimetres
COPD	Chronic Obstructive Pulmonary Disease

CPET	cardiopulmonary exercise test
CRQ	Chronic Respiratory Disease Questionnaire
CRQ-SR	Chronic Respiratory Disease Questionnaire - Self Report
CTU	Clinical Trials Unit
EE	energy expenditure
e.g.	for example
ESWT	Endurance Shuttle Walk Test
et al	and others
FEV_1	forced expiratory volume in one second
FVC	forced vital capacity
GOLD	Global initiative for chronic Obstructive Lung Disease
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HCP	healthcare professional
HR	heart rate
HRQoL	health related quality of life
ICS	inhaled corticosteroid
i.e.	id est ‘’that is’’
IQR	inter quartile range
ISWT	Incremental Shuttle Walking Test
ITT	intention to treat
kcal	kilocalories
kg	kilograms
l	litres
LABA	long-acting $beta_2$ agonist

LAMA	long-acting muscarinic antagonist
lb	pounds
LINQ	Lung Information Needs Questionnaire
l/min	litres per minute
LTOT	long-term oxygen therapy
m	metre(s)
MCID	minimal clinical important difference
METs	metabolic equivalents
mins	minutes
MRC	Medical Research Council
n=	number is
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NRT	nicotine replacement therapy
NS	none significant
p<	probability of less than
p≤	probability of less than or equal to
PA	physical activity
PAL	physical activity level
PaO_2	partial pressure of oxygen in arterial blood
PASW	Predictive Analytics Software
PCRN	Primary Care Respiratory Network
PhD	Doctor of Philosophy
pm	post meridian "after midday"
PR	pulmonary rehabilitation

PRAISE	Pulmonary Rehabilitation Adapted Index of Self-Efficacy
QOL	quality of life
r=	correlation coefficient
RCT	randomised controlled trial
RfPB	Research for Patient Benefit
SAB	SenseWear Armband
SABA	short-acting $beta_2$ agonist
SD	standard deviation
SE	standard error
sec	seconds
SGRQ	St George's Respiratory Questionnaire
SM	self-management
SPACE	Self-management Programme of Activity Coping and Education
SpO_2	saturation of peripheral oxygen
SPSS	Statistical Package for the Social Sciences
TEE	total energy expenditure
UC	usual care
UHL	University Hospitals of Leicester NHS Trust
UK	United Kingdom
v.	version
VO_2	oxygen consumption
VO_2max	maximal oxygen consumption
VO_2peak	peak oxygen uptake
vs.	versus

W	watt(s)

Chapter 1 Introduction

1.1 Background

Chronic Obstructive Pulmonary Disease (COPD) is the third leading cause of death worldwide, and poses significant financial burden on healthcare systems. In the UK direct costs were estimated at around £800 million per year (Department of Health 2004), although this is likely to have risen since.

Historically healthcare has developed a reactive approach, designed on patient initiated contact in order to diagnose and treat threats to health. However, with people living longer the prevalence of chronic disease has risen. The needs of people living with long-term conditions are different from those with acute disease, and are not well met through this model of healthcare. The Chronic Care Model (CCM) suggests a shift away from the paternalistic approach, towards a more patient-centred style (Wagner 1998).

Self-management is incorporated within the CCM as one of its central components. Self-management support aims to improve patients' disease knowledge, self-efficacy and develop skills which will lead to health-enhancing behaviours and better patient outcomes (Bourbeau et al. 2004). Self-management programmes for long-term conditions, such as diabetes and arthritis, are now well established in the clinical pathways of care. In COPD, however, the evidence is lacking (Barlow et al. 2002) and how self-

management should be provided is less clear. There is currently no standardised approach to self-management support for COPD in the UK.

Some of the challenges in the current COPD self-management literature lie around the various interpretations of what self-management programmes should include, and when they should be provided. Many programmes have been initiated following hospitalisation for an exacerbation (Bourbeau et al. 2003; Bucknall et al. 2012; Fan et al. 2012). This is quite far within the disease progression considering diabetes self-management is usually provided within a few weeks of diagnosis. While some self-management programmes have been as brief as an action plan or a single education session (McGeoch et al. 2006; Rice et al. 2010; Watson et al. 1997), others have been far more comprehensive and included supervised education and exercise for up to two years (Monninkhof et al. 2003). Drawing comparisons between these extremes makes it particularly challenging to review the literature and make recommendations.

Despite recognition within the literature of the importance of self-management on health behaviour change, few studies have reported this. This may be because self-management of COPD requires mastery of such an extensive range of behaviours, including but not limited to: exercise, physical activity, smoking cessation, chest clearance, breathing control, energy conservation, inhaler technique, medication adherence, dietary intake and anxiety management. Some of these behaviours may be more easily measured than

others. This thesis focuses on health behaviours which have been shown to have the most important impact on clinical outcomes.

Physical activity is one of these behaviours which will be more closely examined in this piece of work. Technological advances have increased the application of accelerometry to measure objectively physical activity. Recent studies have used accelerometers to demonstrate that people with COPD have reduced activity levels and this may be important to their long-term outcomes (Garcia-Aymerich et al. 2009; Garcia-Aymerich et al. 2003; Waschki et al. 2011). These activity monitor devices, however, provide enormous amounts of data, and there are deficits within the literature as to how best to use these data to make clinical inferences.

1.2 Aims and objectives

This thesis aims to address deficits in the current body of literature in self-management for COPD. A Self-management Programme of Activity Coping and Education - SPACE FOR COPD- is a new self-management programme. This thesis evaluates the effectiveness of this programme in a randomised controlled trial (RCT) in primary care, compared with usual care alone. The primary outcome was pre-specified as Health Related Quality of Life (HRQoL), and was evaluated alongside a range of secondary measures used to reflect the range of self-management skills required and the possible impact.

The hypothesis was that SPACE FOR COPD would confer greater gains in HRQoL when compared with usual care alone.

Furthermore, the variety of outcome measures used in this trial permitted the opportunity to explore a number of other research objectives, which are:

- To review and synthesize the literature and to propose a model of self-management that can be used to inform future research and clinical practice.
- To observe the impact of SPACE FOR COPD on exercise performance, psychological function, physical activity, knowledge and self-efficacy.
- To explore physical activity characteristics in a population of people with COPD managed in primary care.
- To examine factors that may be associated with a change in physical activity following SPACE FOR COPD.

1.3 Structure and setting

The work of this thesis is derived from a National Institute for Health Research for Patient Benefit (NIHR-RfPB) funded study. The grant was awarded to University Hospitals of Leicester (UHL) NHS Trust. The research was conducted between UHL alongside Leicester, Leicestershire and Rutland Primary Care Trusts and Coventry Teaching Primary Care Trust. The study was supported as one of the projects of the Leicestershire Northamptonshire and Rutland National Institute for Health Research Collaboration for Applied

Health Research and Care (LNR NIHR CLAHRC). Study recruitment was supported by the Primary Care Research Network (PCRN).

The protocol of the study had been written prior to my participation in the study by Professor Sally Singh. I was employed by UHL under the RfPB grant as the lead researcher on the study. My role was to over-see the day-to day running of the trial, liaise with other bodies, screen, consent and perform baseline assessments of patients, randomise participants, provide the SPACE FOR COPD intervention to patients, and to arrange follow-up. Another physiotherapist, Vicki Warrington, also worked on the study, for whom I was responsible in supervising. Vicki Warrington also consented and assessed patients, and as a blinded assessor, performed all the follow-up assessments.

The aims and objectives of this thesis are addressed in chapters 2 through 7. Chapter 2 is a review of the current literature in the area and outlines the gaps in knowledge. This identifies the rationale for this work and adds clarity to the literature. The methods of the trial are described in detail in chapter 3. Chapter 4 evaluates the short-term impact of SPACE FOR COPD at six weeks and chapter 5 evaluates the medium-term effects at six months. Both chapters 4 and 5 address the impact on HRQoL, exercise performance, psychological function, knowledge and self-efficacy. The physical activity characteristics of the population are examined in chapter 6, and chapter 7 evaluates the impact of SPACE FOR COPD on physical activity and explores factors which may contribute to a change in physical activity. Finally, chapter

8 considers key themes from the trial findings, study limitations and areas for future research.

Chapter 2 Literature review

2.1 Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) is a term which has been used to describe a group of diseases, including conditions known as chronic bronchitis and emphysema (Department of Health 2010). It is characterized by airflow obstruction which is usually progressive, not fully reversible and does not markedly change over a few months (National Institute for Clinical Excellence 2010). Diagnosis of COPD is based on a multi-dimensional assessment of a history of symptoms, physical examination and confirmation of the presence of airflow obstructive from spirometry (National Institute for Clinical Excellence 2010). Severity of the disease can be described by the degree of airflow limitation. The forced expiratory volume (FVC) and forced expiratory volume in one second (FEV_1) are measures derived by spirometry that express airflow limitation. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) has developed classifications of severity based on the FEV_1 and FVC [table 2.1 (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013)]. Chronic lower respiratory disease was the fourth leading course of death for in 2010 in the UK (Office for National Statistics 2011) and is expected to be the third leading cause of death by 2020 (Healthcare Commission 2006).

Table 2.1 GOLD classification of COPD disease severity (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

2.1.2 Risk factors

COPD is caused by exposure of the lungs to noxious agents, and it is accepted that smoking is the dominant risk factor (Department of Health 2010; Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013; National Institute for Clinical Excellence 2010). Exposure to other stimulants in industrial environments where hazardous agents can be inhaled has been acknowledged as a contributory factor (Blanc and Toren 2007). Those with an inherited pre-disposition of early onset of emphysema are also at risk, as well as people who have had a previous diagnosis of asthma (Department of Health 2010). Burning of biomass fuels, such as coal or straw, in poorly ventilated homes has also been identified as a global risk factor for developing COPD (Mannino and Buist 2007).

2.1.3 Pathophysiology

Pathological changes occur within individuals who have COPD, which include chronic airway inflammation, systemic inflammation and destruction of alveoli (Roth 2008; Willemse et al. 2005). It is believed these changes occur largely due to exposure to cigarette smoke (Bourdin et al. 2009; Roth 2008; Sutherland and Martin 2003), and are initiated long before symptoms are present (Sutherland & Martin 2003). Studies have established that smoking is associated with an increased infiltration of neutrophils and macrophages in the lung which are responsible for modulating behaviour of epithelial cells, fibroblasts and smooth muscle (Bourdin et al. 2009; Roth 2008). This initiates an increased inflammatory response which causes destruction of the elastic tissue in the alveoli and parenchyma, and results in loss of elastic recoil (Sutherland & Martin 2003). Although cigarette smoke is the primary cause, once the disease is established, the inflammatory process continues, even beyond smoking cessation (Willemse et al. 2005).

2.1.4 Clinical features

A spectrum of physical and psychological symptoms has been reported in people with COPD. The most common physiological symptoms are breathlessness, otherwise called dyspnoea, reduced exercise tolerance, cough, fatigue and production of phlegm (Department of Health 2010). In the early stages of the disease symptoms may be mild or even absent (National Institute for Clinical Excellence 2010) and there is usually a progression over time. Studies have shown that symptoms, particularly the level of dyspnoea, are more important for determining quality of life than the degree of airflow

obstruction (Bentsen et al. 2008; Hajiro et al. 1999). Health status is impaired in people with COPD (Wilke et al. 2012) and both physical and mental well-being diminishes with increasing number of symptoms (Voll-Aanerud et al. 2008). Symptoms may be variable on a day-to-day basis, and differ between individuals (Pauwels and Rabe 2004).

Breathlessness is usually a symptom most commonly reported by the patient (National Institute for Clinical Excellence 2010), and is associated with anxiety and fear (Bailey 2004) which can lead to avoidance of activity and a progressive loss of cardiovascular fitness and skeletal muscle de-conditioning (National Institute for Clinical Excellence 2010). Although exercise intolerance may not be reported as often by the patient, it is an important clinical feature of the disease, and contributes significantly to the risk of mortality (Celli et al. 2004). The severity of dyspnoea can be stratified by the Medical Research Council (MRC) Dyspnoea Scale [See table 2.2 (Fletcher et al. 1959)].

Table 2.2 Medical Research Council Dyspnoea Scale (Fletcher et al. 1959)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

More recently GOLD has developed a model for patient stratification which incorporates both disease severity and symptoms (Global Initiative for Chronic Lung Disease (GOLD) 2011). Figure 2.1 illustrates the four possible classifications which combine either FEV_1 or exacerbation frequency with dyspnoea score on the MRC scale or score from the COPD Assessment Tool (CAT), which is a measure of health status (Jones et al. 2009).

Figure 2.1 GOLD 2011 disease severity classification [Global Initiative for Chronic Lung Disease (GOLD) 2011]

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Acute exacerbation (AE) of COPD is an important event for an individual with COPD (National Institute for Clinical Excellence 2010). Definition of an AE is generally accepted as a sustained worsening of symptoms over and above day-to-day variation, is of acute onset, and may require additional treatment (Burge and Wedzicha 2003). Symptoms include cough, increased sputum and sputum purulence(Anthonisen et al. 1987). Those who have frequent exacerbations (≥ three per year) are likely to have a worse prognosis (National Institute for Clinical Excellence 2010; Suissa et al. 2012). Studies have shown that increased frequency of exacerbations is associated with an accelerated decline in lung function (Celli et al. 2008; Donaldson et al. 2002). Health related quality of life (HRQoL) is reduced during an AE and can take several months to improve, despite disease stabilisation (Spencer et al. 2001). Decreased physical activity is a feature which may be present in the days prior to AE (Donaldson et al. 2005) and may remain below baseline levels a month later (Pitta et al. 2006). Severe exacerbations have been shown to have a negative impact on mortality (Soler-Cataluna et al. 2005). In the UK in 2008, 13.9% of people with COPD died within three months of a COPD-related hospitalisation, and it is thought that approximately 25% of those admitted to hospital will die within one year (The Royal College of Physicians, The British Thoracic Society and The British Lung Foundation 2008; The Royal College of Physicians and the BritishThoracic Society 2004).

2.1.5 Prevalence

The precise number of people living in the UK with COPD varies between sources. COPD registers, which are kept by general practitioners, recorded

710,000 cases in 2009 (Department of Health 2009), however the accuracy of these documents is unknown. Previous reports estimate that approximately 900,000 people living in the UK have a diagnosis of COPD (Healthcare Commission 2006). Both of these figures are significantly lower than the suggested prevalence of three million which has been estimated from smoking rates (Stang et al. 2000). This implies that there may be around two million people in the UK with COPD who remain undiagnosed; these are known as the 'missing millions' (Department of Health 2010).

Rates of COPD are associated with deprived communities, particularly in men working in the routine/manual sector (Department of Health 2004). It is thought this is due to higher smoking rates in this group (26% compared with 15% in managerial/ professional trade), that smoking is taken up at an earlier age and that this group have an increased likelihood of exposure to environmental hazards (UK National Statistics 2007).

2.1.6 Disease burden

Burden to the individual

The symptoms of COPD described in section 2.1.4 can lead to poor physical functioning (Braido et al. 2011), reduced daily physical activity (Pitta et al. 2005b), social isolation and depression (Hanania et al. 2010; Omachi et al. 2009). Health related quality of life is impaired for those with COPD, in comparison to healthy individuals (Schlenk et al. 1998). Increased disease severity is associated with higher levels of disability (Braido et al. 2011) and with poor quality of life (Ferrer et al. 1997). Disease severity, however, is not

an independent determinant of quality of life , and other factors including exercise performance, dyspnoea, self-reported disability and depression are also influential (Moy et al. 2009).

Burden to the family

The impact of the disease extends to the patients' family, or 'informal caregivers' (Simpson et al. 2010). A shift in relational patterns and roles within the relationship can result in feelings of social isolation and a decreased ability to cope (Seamark et al. 2004; Simpson et al. 2010). Powerlessness, anger, grief, sadness, depression and shame have been identified as negative emotional reactions to the process of caring for a family member with COPD (Simpson et al. 2010). Spouses have identified that the burden of living with COPD are shared, and the marital relationship can become strained (Seamark et al. 2004). It has been argued that family who are responsible for caring for someone with COPD should be provided with social and professional support to address deficiencies in knowledge and to raise awareness of their potential roles (Spence et al. 2008).

Burden to the healthcare system

COPD poses a significant public health problem, and therefore the burden on the healthcare system is substantial. COPD is among the most costly conditions treated by the NHS (National Institute for Clinical Excellence 2010). In 2004 the Chief Medical Officer published a statement which reported annual direct costs of COPD of around £800 million (Department of Health 2004). The impact on lost productivity was high with 24 million work days lost

each year, which accounted for indirect costs of approximately £2.7 billion (Department of Health 2004). Wouters (2003) studied the costs associated with COPD using data from the 'Confronting COPD' survey. Annual direct per patient costs of COPD in the UK were estimated at £833, which was the median cost among the range of countries (Wouters 2003). Costs associated with COPD escalate as the disease progresses, particularly in the most severe stage [See table 2.3 (Healthcare Commission 2006; National Institute for Clinical Excellence 2010)].

Table 2.3 Average costs per person for general management and management of an acute exacerbation of COPD (Healthcare Commission 2006; National Institute for Clinical Excellence 2010)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

2.2 Physical activity

2.2.1 Physical activity and COPD

As previously discussed, physical activity is believed to be an important behaviour in individuals with COPD. Physical activity is reduced for those with COPD compared to healthy controls (Coronado et al. 2003; Hernandes et al. 2009; Sandland et al. 2005; Waschki et al. 2012), in both duration and

intensity (Coronado et al. 2003;Hernandes et al. 2009;Pitta et al. 2005b). This decline is present in early stages, and significant reductions are seen even at GOLD stage II (Waschki et al. 2012; Watz et al. 2009). Activity levels decline further as disease severity, in terms of lung function, progresses (Waschki et al. 2012; Watz et al. 2009).

A study by Garcia-Aymerich (2006) used activity questionnaires in 2,386 patients with COPD, and found that individuals with 'very low' activity had an increased risk of respiratory related hospital admissions and mortality. This was supported by later findings by Waschki et al. (2011) who measured activity with accelerometers and found that the physical activity level (PAL) was the strongest predictor of all cause mortality. Physical inactivity has also been associated with worse quality of life (Esteban et al. 2010; Garcia-Aymerich et al. 2004; McGlone et al. 2006), increased disability (Katz et al. 2011) and higher exacerbation rates (Waschki 2012).

The implementation of regular physical activity for the general population is endorsed by the UK government (Bull 2010) and the World Health Organisation (World Health Organisation 2010) due to its relationship with development of chronic diseases such cardio-respiratory disease, metabolic disease, cancers and mental health as well as all cause mortality. It is widely accepted that higher levels of physical activity are beneficial, and that these benefits can be significant. The guidelines from the American College of Sports Medicine (ACSM) are resoundingly accepted as the benchmark for the quota of physical activity required for a healthy lifestyle. The most recent

guidelines were produced for adults (Haskell et al. 2007) and replicated for older adults or adults with chronic illness (Nelson et al. 2007). The former recommends that adults should undertake at least 30 minutes of moderate intensity activity five times per week or 20 minutes of vigorous activity at least three times per week, or a combination of both. Moderate intensity is defined using metabolic equivalents (METs). One MET represents resting energy expenditure. A threshold of ≥3 METs <6 METs is used to define moderate activity and ≥6 METs for vigorous intensity. The guidelines for the older adult were updated to reflect the fact that what an older adult, or an adult living with a chronic condition considered to be 'moderate', may not be the same in absolute terms as what a young, healthy adult would consider 'moderate'. These guidelines therefore recommend that on a zero to 10 Likert scale of effort, moderate activity would be scored around five to six, and vigorous around seven or eight. UK policy supports these guidelines, and recommends that 150 minutes of moderate or vigorous activity should be conducted per week (Department of Health 2013).

2.2.2 Measuring physical activity

Considering that physical activity may play an important role in the disease progression and outcomes for individuals for COPD, appropriate methods of measurement are required. One's daily activity may be influenced by many individual factors including employment, health status, co-morbidities, weekday (Matthews et al. 2002), and time of the year (Sewell et al. 2010), and therefore measuring it may be challenging, therefore several approaches may be taken.

Questionnaires

There have been many questionnaires developed which attempt to measure physical activity, and several have been validated in COPD. While some questionnaires (Sallis et al. 1985; Taylor et al. 1984) have been shown to correlate well with calorimetry, others have been used alongside monitoring devices with poor correlation found between the two (Donaire-Gonzalez et al. 2011; Pitta et al. 2005a; Steele et al. 2000). Questionnaires have been used extensively, and several landmark studies in the field of physical activity have used this method of data collection (Garcia-Aymerich et al. 2003;Garcia-Aymerich et al. 2006; Watz et al. 2009). Questionnaires are likely to be subject to re-call bias, and are likely to reflect the activity that the individual perceives they do, rather than what they actually do. When using physical activity questionnaires, or interpreting the data, it is important to remain aware of this discrepancy.

Exercise tests

While exercise tests may not actually measure daily physical activity, they may describe capacity for activity, and have long been referred to as surrogate markers for physical activity. A greater performance on exercise testing indicates a higher level of fitness, which might afford a greater ability to undertake more physically demanding tasks. It is important to recognise, however, that this may not always be the case, and that just because one has the ability to undertake activities does not mean that one does. There is a variety of exercise testing which are commonly employed. The gold standard of exercise tests is a cardiopulmonary exercise tests (CPET), which is usually

performed on a treadmill or cycle ergometer (Palange et al. 2007). Field tests have been developed which are considered more practical in a clinical setting. The ISWT (Singh et al. 1992) and the 6MWT (Butland et al. 1982) are the most well established of these tests in individuals with COPD.

Activity monitors

Over the past decade the development of devices for measuring activity has been attractive to researchers in COPD. However, with such a range of monitors available, and a variety of data output, there is currently no established best practice for their application. Devices range from simple pedometers which count steps, to complex multi-axial accelerometers which measure energy expenditure, vector magnitude units (VMU), or time spent in various positions or activities. There are a number of properties which need to be accounted for in selecting a monitor.

Firstly, it should be considered if the output of the monitor is to be concealed from the individual wearing it. Devices which display data may not be appropriate when the monitor is to be used as an outcome measure, and may be more suitable as part of an intervention, such as using pedometers which display step counts. While some might argue that wearing a monitor may intervene in influencing physical activity, this has not been found to be the case when Sandland et al. (2005) documented no difference in activity level between those who knew why they wore a monitor and those who did not.

Another important feature of monitor selection is the nature of the data it provides. Step count is now commonly reported by many monitors. While the Mini-Mod (MM) and SenseWear Armband (SAB) monitors have been shown to report step count accurately, at slower speeds the validity of these monitors is less reliable (Furlanetto et al. 2010; Hill 2010a; Langer et al. 2009). This is important considering that people with COPD predominantly ambulate at slower speeds. It might also be considered that using step count to describe physical activity may be limited as it does not consider non-ambulatory activities. For example, some patients with COPD may find tasks such as getting dressed, washing, cooking or doing the gardening exert considerable energy, and would not be captured on step count information.

There are several monitors that are able to provide estimates of energy expenditure. The SAB and MM measure this in terms of metabolic equivalents (METs), the Tritrac R3D, Actigraph and Actiwatch measure Vector Magnitude Units (VMU). The gold standard of measuring energy is through indirect calorimetry (IC) which measures gas exchange (Ferrannini 1988). The SAB has been validated against IC and has shown to be sensitive to detecting changes in energy expenditure across a range of tasks (Cavalheri et al. 2011; Hill et al. 2010a). Hill and colleagues (2010a) demonstrated that the difference between energy expenditure measured by SAB and IC was -0.2 METs ($p=0.21$, limits of agreement 1.3 METs) in a combination of slow and fast walking, standing, sitting and lying. Langer et al. (2009) also found the MM estimated energy expenditure well against IC, however it was not as sensitive as the SAB for detecting moderate energy expenditure.

A comparison of six of the most commonly used accelerometers was recently conducted (Van Remoortel et al. 2012). Patients with COPD were recruited across four sites and wore six activity monitors simultaneously: the Kenz Lifecorder, Actiwatch, RT3, Actigraph GT3X, Dynaport MiniMod and the SenseWear Armband. A protocol of tasks was completed, including walking, sitting, standing, lying and stairs, while wearing a portable device for measuring indirect calorimetry. The Dynaport MiniMod, Actigraph GT3X and SenseWear Armband were the most valid monitors during these tasks.

In activity monitoring, other methodological factors must also be considered. The minimum duration an activity monitor should be worn for each day in order to be representative of an individual's daily activity has not been ascertained. While several studies have deemed 12 hours to be adequate (Breyer et al. 2010; Pitta et al. 2008; Sewell et al. 2010), others report accepting data where the monitor has been worn for less (Coronado et al. 2003; Mador et al. 2011). Additionally, if measurements are taken at more than one time point, it is necessary to consider whether a standardised time frame of measurement should be applied. In standardising the measurement period, e.g. 12 hours pre and post, we can be more confident that any observed change is as a result of an intervention. By having a standardised time frame, however, any activity undertaken outside of that period is not considered in the analysis, which may lead to an underestimation of activity levels.

There has been more attention in the literature to establish the number of days required for accelerometry measurement in order to accurately represent average physical activity levels. In various COPD populations, this has been estimated from as little as two days up to 10 days (Hart et al. 2011; Hecht et al. 2009; Tudor-Locke et al. 2005). The overall message from these papers appears to be that the longer it is worn for the better (Hecht et al. 2009), but that a minimum of three days is required (Hart et al. 2011;Tudor-Locke et al. 2005).

2.3 General management of COPD

It is recommended that a symptom based approach should be adopted in determining the management of each person with COPD (National Institute for Clinical Excellence 2010). Clinical features of the condition may be variable over time and the course of treatment should be modified in response to these changes. Currently, the most widely adopted strategies include smoking cessation, pharmacotherapy and pulmonary rehabilitation.

2.3.1 Smoking cessation

Exposure to cigarette smoke is the leading cause of COPD, triggering an inflammatory response in the lung tissue (Bourdin et al. 2009). Although increased inflammation continues after smoking cessation (Willemse et al. 2005), stopping smoking slows the decline in FEV_1 (Anthonisen 1989; Fletcher and Peto 1977; Hoogendoorn et al. 2010; Scanlon et al. 2000) and has a positive impact on symptoms (Kanner et al. 1999). Although mortality rates are still higher for ex-smokers than for never smokers, studies indicate

that mortality declines progressively following smoking cessation (Godtfredsen et al. 2008). The current NICE guidelines for COPD recommend that all COPD patients who are current smokers should be advised to quit, offered nicotine replacement therapy (NRT), Varenicline or Bupropion as appropriate, and should have a programme of support provided (National Institute for Clinical Excellence 2010).

2.3.2. Pharmacotherapy

Inhaled therapy is the forefront of pharmacological management for individuals with COPD, aiming to reduce obstruction through dilation of the narrowed airways (National Institute for Clinical Excellence 2010). Although the structural damage caused to the epithelial walls is largely irreversible, inhaled therapy may produce a small increase in FEV_1 (National Institute for Clinical Excellence 2010). These drugs also appear to be effective in reducing both static and dynamic hyperinflation (National Institute for Clinical Excellence 2010), which may be important for exercise intolerance (O'Donnell et al. 2001). There are several types of inhaled therapy, which include; $beta_2$ agonists, anticholinergics and inhaled corticosteroids (ICS). Both $beta_2$ agonists and anticholinergics are often prescribed as either short-acting or long-acting.

It is recommended that the first line of inhaled therapy is a short-acting $beta_2$ agonist [SABA (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013; National Institute for Clinical Excellence 2010)]. In the event that this is not effective at reducing dyspnoea, or if frequent exacerbations persist, and if

the FEV_1 % predicted ≥ 50, then a long-acting muscarinic antagonist (LAMA) or a long-acting $beta_2$ agonist (LABA) should be offered (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013; National Institute for Clinical Excellence 2010). If breathlessness or frequent exacerbations persist, and if the FEV_1 % predicted < 50, then LAMA or LABA+ICS should be offered (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013; National Institute for Clinical Excellence 2010). Both LAMA and LABA+ICS can be used together for individuals who remain breathless (National Institute for Clinical Excellence 2010). LABA+ICS cost around £33 to £41 per month, and a LAMA costs around £35 per month (British National Formulary 2013). Lung function, exercise tolerance, functional capacity, symptoms and side effects should all be monitored to examine the usefulness of the therapy on the individual (National Institute for Clinical Excellence 2010).

2.3.3 Pulmonary rehabilitation

Pulmonary rehabilitation is defined as an individualised programme of care which aims to improve physical activity, psychological functioning, enhance knowledge and improve self-management for those with respiratory impairment (Nici et al. 2006). It is echoed across guidelines that pulmonary rehabilitation should be an interdisciplinary activity and should recognise the needs of each individual (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013 ; National Institute for Clinical Excellence 2010; Nici et al. 2006; Ries et al. 2007).

Pulmonary rehabilitation usually includes a programme of physical exercise training alongside a course of structured education. The exercise programme includes aerobic and strength training and aims to mediate the extra-pulmonary effects of the disease by addressing muscle de-conditioning and exercise intolerance (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013; National Institute for Clinical Excellence 2010). It is important to consider both strength and endurance training as it has been shown there is a cross-over effect of training (Spruit et al. 2002). In addition to physical training, education should be provided in order to equip the individual with the knowledge required to optimally manage their condition on a day-to-day basis.

There may be some overlap between pulmonary rehabilitation and self-management support. It could be argued that a good pulmonary rehabilitation programme is a form of self-management, in so far that it should provide education to assist in decision-making, support patients with the social and psychological ramifications of the disease and provide strategies for long-term behaviour change. This does not mean, however, that all self-management programmes qualify as pulmonary rehabilitation. Self-management has been provided through a spectrum of approaches, and this is discussed further in section 2.5.

A Cochrane Review of pulmonary rehabilitation reviewed 31 RCTs and supported the inclusion of rehabilitation in the management of COPD due to its impact on dyspnoea, fatigue, emotional function and disease control (Lacasse et al. 2006). Exercise is the cornerstone of pulmonary rehabilitation

and gains in exercise capacity are of considerable interest, and are well documented (Griffiths et al. 2000; Pitta et al. 2008; Sewell et al. 2005; Sewell et al. 2006; Troosters et al. 2000). There are clear short-term gains from rehabilitation; however, improvements in HRQoL and exercise performance have been shown to diminish by six to 12 months (Egan et al. 2012; Griffiths et al. 2000; Sewell et al. 2006).

In summary, there are a number of treatment approaches for people with COPD, which may improve lung function, HRQoL, physical function and psychological well-being. It is likely that all, or a combination of these strategies may need to be provided for any individual with COPD. It is common to prescribe inhaled therapy as a first line approach. However, what figure 2.2 shows is that inhaled therapy is more expensive per quality adjusted life year (QUALY) gained than influenza vaccination, smoking cessation and pulmonary rehabilitation. This highlights that although medical management is important, other approaches should not be ignored.

Figure 2.2 COPD value pyramid (NHS Improvement Lung 2013)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

2.4 Chronic care and self-management

2.4.1 Approach to management of chronic illness

Having discussed the current treatments for COPD it is important to consider how the application of these strategies can be approached. In the earliest half of the twentieth century, healthcare systems around the world were developed when the primary threat to health was infectious disease (Creer and Holroyd 2006; World Health Organisation 2002). In 1901 the average life expectancy was 47 years of age and by 1915 63% of the British population died before the age of 60 (Hicks 1999). Chronic diseases were not well understood, and their prevalence was low given that people were more likely to die at an early age (Creer & Holroyd 2006). Thus a paternalistic model of healthcare which was suitable in meeting the needs of acute illness was established and has been embedded in many healthcare systems since (Creer & Holroyd 2006).

A paternalistic model of healthcare requires physician-led decisions about the management of an individual based on medical information (Creer & Holroyd 2006). This model is focused on triage of patients, diagnosis and treatment of symptoms, reliance upon laboratory tests and prescriptions, short appointments, brief education and patient-initiated follow-up (Wagner 1998). It is a reactive form of health care in which the healthcare professional makes active decisions and the patient is a passive recipient of care.

It is acknowledged that current healthcare provision does not reflect changes in society (Holman and Lorig 2004; Wagner 1998; World Health Organisation 2002). The population is aging, with only 12% dying before the age of 60

(Hicks 1999) and the incidence of chronic disease rapidly increasing (World Health Organisation 2002). The characteristics of chronic disease are fundamentally different from acute illness (Holman and Lorig 2004). In contrast to acute conditions, chronic diseases are often of gradual onset, with an undulating course both physically and psychologically and ultimately are without cure (Holman & Lorig 2004). The needs of individuals and families living with chronic health conditions are not well met through the paternalistic model of care which many healthcare systems have adopted (Wagner 1997). Acute care is discontinuous and fragmented (Holman & Lorig 2004), which does not lend itself to a long-term condition that cannot be cured. It seems inevitable, therefore, that healthcare systems which apply acute management strategies to the treatment of chronic disease will fail to meet the complex and on-going needs of long-term conditions (World Health Organisation 2002).

2.4.2 Chronic Care Model

Wagner and colleagues proposed an alternative approach to improve the management of chronic disease (Wagner 1998). The Chronic Care Model [CCM (Figure 2.3)] proposes that healthcare systems must be re-configured to meet the needs and improve outcomes for the chronically ill patient. The model suggests there are key elements required for effective management of chronic disease: self-management, decision support, delivery system design and clinical information systems. These components are based on a collaborative partnership between a prepared, proactive healthcare team and an informed, activated patient.

Figure 2.3 The Chronic Care Model (Wagner 1998)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

2.4.3 Definition and principles of self-management

Self-management has arisen as one of the key components of the CCM. For people living with a chronic condition, they are usually their own primary caregiver, therefore self-management is inevitable (Redman 2004). Lorig and Holman (2003) argue that when living with a chronic condition it is *not* possible to *not* self-manage, it is a question of *how well* one self-manages. The success of that course of management will determine health outcomes for that individual over their lifetime (Holman & Lorig 2004). Given the development of chronic diseases, and the increased burden they impose, it is unsurprising that interest in self-management has developed in recent years.

Defining what self-management is may be challenging. The term is used inter-changeably with self-management support, self-management education, self-care and disease management. This has led to broad interpretation and application as will be discussed later in section 2.5. It may be most useful to characterise self-management by considering what it involves, rather than what it is.

Unravelling individual components which constitute successful self-management and the processes by which it occurs has been attempted (Bourbeau 2008; Corbin & Strauss 1988; Lorig & Holman 2003). So far these concepts rely on theoretical models and clinical experience rather than evidence based trials. Corbin and Strauss (1988) identified three tasks that are necessary for undertaking self-management; i) medical management (such as taking medications or inhalers); ii) role management (adjusting lifestyle and behaviours) and emotional management (dealing with the emotional impacts such as anxiety or depression). These tasks have been widely accepted as important aims of self management (Lorig & Holman 2003;Redman 2004).

While the model of Corbin and Strauss considers what self-management strives to achieve, it does not consider the processes by which it occurs. Lorig et al. (Lorig & Holman 2003) identify five core self-management skills which are discussed below.

Problem-solving

Patients with long-term conditions should be taught problem-solving skills. The role of the healthcare professional is to teach the patient how to examine the problem, how to define it, deconstruct it and how to find a range of solutions. It is suggested patients finding their own solutions is preferential to them being offered by the professional. By equipping the patient with problem-solving skills the individual is able to apply those skills and find solutions to any given problem they may face on a day-to-day basis.

Decision-making

Decision-making is a process undertaken by all individuals on a daily basis. These decisions may be better judged with access to enough and appropriate knowledge. The responsibility often lies with the healthcare professional to provide access to this knowledge. However, decisions are not usually made solely on disease-specific knowledge alone. Thorne and colleagues (Thorne et al. 2003) accumulated qualitative data from studies that were carried out among people with diabetes (Paterson and Thorne 2000), HIV and multiple sclerosis (Paterson et al. 2002). They conducted interviews with individuals who had lived with a chronic disease for many years and who believed they were effective in their decision-making abilities. Common across all individuals was the recognition that the disease was chronic and an understanding that disease outcomes would be directly related to self-care decisions was instrumental to the motivation to take control of their disease. Self-monitoring of symptoms, personal experience and understanding their

own circumstances were identified as being important to the decision making process.

Utilisation of resources

Self-management programmes should teach individuals how to find, select and use sources of help such as the internet, library services or programmes such as smoking cessation or support groups. To acquire this skill, self-management programmes should not just *tell* people about resources but teach them *how* to use them. There may also be a requirement to teach people how to use several resources at once, rather than the common approach of using one at a time.

Collaborative Partnership

The fourth skill is formation of partnerships between the patient and healthcare professionals. This might also be referred to as collaborative or shared care, and features in the CCM. It suggests that there are two experts in the consultation room; the physician and the patient (Creer & Holroyd 2006). The role of the physician as the decision-maker and of the patient as the passive recipient of care, as often seen in acute care management, should no longer apply (Holman & Lorig 2004). In collaborative care the physicians' role is not to get patients to behave in the way they wish them to (Bodenheimer et al. 2002) but to add their medical knowledge to what patients already know about their own capabilities and goals (Bodenheimer et al. 2002) and to act as a teacher and provide guidance (Holman & Lorig 2004). This approach is based on addressing the perceived problems of the patient

and not what the healthcare professional perceives the problems to be (Bodenheimer et al. 2002).

Taking Action

Finally, taking action is identified as the fifth core skill. Schreurs and colleagues (2003) believe that disease-specific goals and patients' own life goals may pose barriers to one another. Therefore, all goals should be made by the patient rather than the practitioner so that they are more likely to be realistic for the individual. There is evidence to suggest that goal-directed behaviour is enhanced when planning of the behaviour takes place (Gollwitzer 1999). This is supported by planned behaviour theory, which suggests that individuals can plan for barriers that may threaten goal achievement (Schreurs et al. 2003).

2.4.4 Mechanisms of self-management

Self-efficacy is the cornerstone of many psychological behavioural frameworks (Ajzen 1991; Miller and Dollard 1941; Rosenstock 1966). Lorig and colleagues (2003) propose that self-efficacy is a mechanism by which effective self-management can be achieved. In his landmark paper Albert Bandura describes self-efficacy as the perception of one's ability to perform a task or behaviour in any given situation, determines whether a behaviour will be initiated, how much effort will be spent and how long the behaviour will be sustained (Bandura 1977a).

Self-efficacy in relation to health behaviour change has been examined in a variety of healthcare contexts (Strecher et al. 1986). A review of studies which examined self-efficacy in smoking cessation, weight control, contraception, alcohol misuse and exercise was conducted by Stretcher et al. (Strecher et al. 1986). They concluded that self-efficacy was a consistent predictor of both short-term and long-term success in behaviour change. As successful self-management of chronic disease often requires changes in health behaviour, it is plausible that enhanced self-efficacy might strengthen this process.

Figure 2.4 Self-efficacy model (Bandura 1977a)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

The framework from Bandura (Bandura 1977a) illustrated in figure 2.4 suggests that behaviour change is a result of 1) efficacy expectations of one's ability to perform a behaviour and 2) the expectations of the outcome of engaging in that behaviour. The model in figure 2.5 is similar to the process proposed by Bandura, insofar that self-efficacy supports behaviour change. However, the model by Bourbeau et al. (2004) suggests that the acquisition of knowledge and skills are important for supporting self-efficacy in the behaviour change process. Studies have demonstrated that education may improve disease knowledge (Hill et al. 2010b; White et al. 2006), although as

yet there is no research in a COPD population to suggest that improved knowledge leads to behaviour change.

Figure 2.5 Model of behaviour change (Bourbeau et al. 2004)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Manipulation of self-efficacy may be possible and may improve adoption of health behaviours (Kaplan et al. 1984). The models by both Bandura and Bourbeau et al. suggest that several approaches can be used to enhance self-efficacy. Bandura's model advocates that in order to improve self-efficacy, one's confidence that they are able to achieve a particular behaviour and their confidence that in doing the behaviour will lead to a desirable outcome must be raised. Bourbeau's suggests that building knowledge and skills are important. These models complement each other, as the combination of these strategies offers both psychological and practical approaches to enhance self-efficacy.

2.4.5 Motivational Interviewing

Motivational Interviewing (MI) is a counselling technique first described by Miller in 1983 (Miller 1983). It is a technique he conceptualized from his own experience, and from drawing on previous published theories, which focuses on an empathic, person-centred style and strengthening the clients' own change talk, rather than the norm of confrontational style counselling (Miller 1983). There are many features of MI which make it potentially useful in supporting self-management and behaviour change.

The spirit of MI has been described as collaborative rather than confrontational, should evoke the individual's motivation rather than to instil it and should preserve the individual's autonomy. It can be directed towards people who are ambivalent or reluctant to change their behaviour, and the counselling style should help the individual to recognise their current problems and to develop solutions, with the overall aim of improving intrinsic motivation to change (Rubak et al. 2005). MI is based on four key principals of expressing empathy, developing discrepancy, rolling with resistance and supporting self-efficacy (Miller and Rollnick 2002).

A systematic review in 2005 (Rubak et al. 2005) assessed 72 RCTs in which the MI intervention was deemed to be in congruence with the description of MI by Miller and Rollnick (Miller & Rollnick 2002). 47 of these studies were for addiction, while the remaining 25 were for physiological problems. Median duration of MI sessions was 60 minutes and the likelihood of gaining a treatment effect increased with number of encounters. Overall, a statistically

significant treatment effect was found in 74% of trials. The likelihood of a positive effect was enhanced by a prolonged follow up period.

A second review also analysed 72 studies, however was not limited to RCTs (Hettema, Steele and Miller 2005). They found an effect size of 0.77 (95% CI: 0.35-1.19) zero to one month post MI treatment. This diminished over time to 0.11 (0.06-0.17) at follow-ups over 12 months. Success of treatment was not predicted by treatment duration, purity of the intervention, training or support. There were no detrimental effects reported from MI treatment in either review. Both of these reviews, however, were largely of studies of substance misuse and addiction. The application and effectiveness of MI in behaviour change, or lifestyle, interventions may differ and should be considered.

Although the literature of MI in chronic disease health management is not as well developed as it is in substance misuse, there have been some studies. In a study of individuals at risk of chronic disease undergoing a self-selected opt-in MI and education intervention, improved self-efficacy and health status was observed compared with individuals who chose not to opt-in to the treatment (Linden et al. 2010). It cannot be concluded, however, whether it was the MI or the education advice received that was responsible for these changes. Hawkins (2010) conducted an RCT of a diabetes self-management education programme (DSME) combined with MI compared with a control group who received healthy lifestyle advice. They found that the intervention group improved their glycaemic control and demonstrated significant improvements in self-efficacy and disease knowledge. Another study for diabetes showed

that the patients of GPs trained in MI showed significantly enhanced autonomy, increased motivation to change and reported having more information from their GPs than did a group of patients whose GP was not trained in MI (Rubak et al. 2009). A limitation of these studies is that it is not possible to establish whether it was the MI or the education that was responsible for the changes.

A study in heart failure patients, however, conducted an RCT which compared three groups; MI; standard care and MI plus standard care, with the aim of improving physical activity (Brodie et al. 2008). Only those in the MI group and MI plus standard care group significantly improved their activity levels, suggesting that MI was the feature important in bringing about behaviour change.

Although the evidence-base in chronic disease interventions is small, there is some indication that there may be additional benefits of supplementing care with MI. As yet, little research has been done on using MI to support behaviour change in self-management programmes for COPD.

2.4.6 Outcomes of self-management

Appropriate outcome measures which accurately reflect the aims self-management should be selected in evaluating the programme.

Knowledge

As previously described, appropriate knowledge is required in order to aid decision-making in self-management. Self-management programmes should therefore aim to promote education. Knowledge can be measured directly with questionnaires. The Bristol COPD Knowledge Questionnaire [BCKQ (White et al. 2006)] and the Lung Information Needs Questionnaire [LINQ (Hyland et al. 2006)] have been validated in individuals with COPD. These questionnaires have both been used in pulmonary rehabilitation studies, and have shown to be sensitive to change (Jones et al. 2008; White 2006). As yet, these tools have not been used in any self-management studies.

Health Behaviour

There are a range of behaviours which reflect improved self-management in people with COPD. Smoking, physical activity and exercise are the most important behaviours, in terms of health outcomes. However, there may be a wealth of other behaviours and skills, such as chest clearance, breathing control, medication adherence, inhaler technique, diet and stress management which may be important for an individual.

Quality of Life

Quality of life is impaired in people with COPD (Spruit et al. 2007), and the aim of self-management support is to improve quality of life through positive health behaviour change. There are many tools available to measure quality of life, as both generic and disease specific measures. The choice about which to use might best be made based upon the population to which they are

being applied. This allows for disease-specific aspects of quality of life to be assessed. For individuals with COPD the two most common measures of HRQoL are the St. George's Respiratory Questionnaire [SGRQ (Jones, Quirk and Baveystock 1991)] and the Chronic Respiratory Questionnaire [CRQ (Guyatt et al. 1987)]. Both of these measures have been validated and shown to be sensitive to change in a COPD population (van Rutten, Roos, & van Noord 1999). The SGRQ is comprised of four domains; symptoms, impact, activity and total. The range for each domain is zero to 100, with lower scores indicating a higher quality of life (Jones, Quirk, & Baveystock 1991). The CRQ is also comprised of four domains; dyspnoea, fatigue, emotion and mastery. Each domain is scored from one to seven, with higher scores indicating a higher quality of life (Guyatt et al. 1987). The questionnaire has also been developed in a self-report format (Williams 2001) which has been shown to be sensitive to change (Williams et al. 2003). The minimal clinical important difference (MCID) for this questionnaire has been estimated as 0.5 (Jaeschke et al. 1989). Several self-management programmes have used both the CRQ and the SGRQ (Bourbeau et al. 2003;Effing et al. 2011; Khdour et al. 2009), although neither tool has been found to be superior (van Rutten, Roos, & van Noord 1999)

Anxiety and depression has a high prevalence in individuals with COPD (Janssen et al. 2010). It might be anticipated that if self-management strategies are adopted, and behaviour change is embraced, then symptoms of anxiety or depression may be reduced following a self-management programme. There are several tools available, however, the most commonly

used in people with COPD is the Hospital Anxiety and Depression Scale [HADS (Zigmond and Snaith 1983)]. The HADS is scored on a scale of zero to 21, and has two separate scores for both anxiety and depression. Scores within the range of eight to 10 signify a possible presence of anxiety/ depression and scores within the range 11-21 signify a probably presence of anxiety/ depression (Zigmond & Snaith 1983). The MCID of the HADS has been estimated at around 1.5 (Puhan et al. 2008).

Healthcare utilisation

It may be anticipated that improved disease knowledge will lead to behaviour change that will ultimately reduce patients' healthcare utilisation. The expectation is that early identification of exacerbations followed by prompt initiation of treatment, such as antibiotics or steroids, will reduce the need to be admitted to hospital. This is a desirable outcome, particularly for commissioners, given the rising costs of COPD.

2.5 Self-management and COPD

2.5.1 Current self-management strategies for COPD

The most recent Cochrane Review of self-management for COPD was published in 2007 (Effing et al. 2007). The review included 15 comparisons from 14 studies, and found that self-management was associated with a significant reduction in hospital admissions with no detrimental effects. There were statistically significant improvements in HRQoL, which did not reach the clinically significant threshold. No effects on number of exacerbations, lung function or exercise capacity were seen. While the authors concluded that

self-management should be recommended, there was significant heterogeneity in the interventions, outcome measures and time to follow-up, suggesting the need for further research.

To date, there has been a variety of interventions aimed at promoting self-management for individuals with COPD. While some of these strategies have openly adopted the title ‘self-management’ others fall under names such as education, home- rehabilitation or disease-management programmes. The name or title applied to an intervention can make the literature difficult to review. As discussed previously, pulmonary rehabilitation programmes may be a form of self-management but not all self-management programmes may qualify as pulmonary rehabilitation. A key distinction of pulmonary rehabilitation is that it should be interdisciplinary, suggesting that there should be some level of supervision from a multi-disciplinary team of healthcare professionals. Self-management may be supervised, but it may also be unsupervised, and there is no such requirement for an interdisciplinary approach.

The Cochrane Review of self-management excluded all studies branded as ‘pulmonary rehabilitation’. There are, however, many programmes which have been labelled as rehabilitation and yet are entirely home-based or unsupervised. Furthermore, the review included studies labelled as ‘self-management’ which provided far more supervision and support than many pulmonary rehabilitation programmes. This following appraisal of the literature

attempts to evaluate studies based upon the contents of the programme rather than the label used to define it.

Studies were included in this review if they were defined by the authors as ‘self-management’. In addition, studies which evaluated an intervention which included education with an unsupervised exercise programme, regardless of what it was called, i.e. pulmonary rehabilitation or home-rehabilitation, were included. In an attempt to exclude studies which were more closely aligned with pulmonary rehabilitation than self-management, studies were excluded if they contained education with supervised exercise, unless it had been pre-defined by the authors as a ‘self-management programme.’

For search terms see Appendix 1. The review has been divided into three sections; education with supervised exercise; education with unsupervised exercise and education with no exercise. Study characteristics are summarised in table 2.4 which are listed in alphabetical order.

Table 2.4 Summary of self-management studies for COPD

Author	Country	n=	Design	Patient characteristics	Intervention	Results	Comments
Bischoff (2012)	Netherlands	165	3 arm parallel RCT	(SM) (C) (RM) Age: 66(12) 64(10) 66(8) FEV_1%: 66(17) 67(18) 63(14) Male n(%):37(67) 28(51) 42(76) Stable, primary care	Supervised education for 2-4 sessions (50 mins per session) Phone contact Action Plan No exercise	Treatment difference at 24mt: CRQ-total:-0.22 (-0.49 to 0.042); CRQ(D):-0.16(-0.54 to 0.21); (F): -0.17(-0.62 to 0.27); (E):-0.31(-0.66 to 0.039); (M):-0.20(-0.55 to 0.14)	Blinded assessment Computer generated randomisation
Bourbeau (2003)	Canada	191	Parallel group multi-centre RCT	(SM) (C) Age: 69.4(6.5) 69.6(7.4) FEV_1: 1.00(0.33) 0.98(0.31) 6MWT: 282(91) 280(90) Male n(%): 50(52) 56(59) Hospitalised within previous 12m	Supervised exercise, one-to-one home visits (1 hr each) for 7-8 weeks Home exercise programme Action plan Phone contact	Treatment difference at 12mt: Admission COPD -39.8 (p=0.01), Other -57.1 (p=0.01) SGRQ(T): at 4mt -4.2(-7.7 to -0.2), at 12mt -2.0(-5.9 to 1.8)	Blinded assessment Randomisation procedure not reported
Boxall (2005)	Australia	60	Parallel group RCT	(SM) (C) Age: 77.6(7.6) 75.8(8.1) FEV_1: 0.79(0.33) 0.89(0.37) 6MWT: 163(60) 148(62) Male n(%): 11(48) 15(65) Elderly, housebound	Supervised exercise and education, 9 one-to-one home visits over 12 weeks	Change at 12mt(SM)v(C): 6MWT:39 v 4.2 (-93.4 to -7.3) p=0.023 SGRQ(T):-5.8 v -1.4 (1.5 to 16.4) p=0.020 Respiratory admission rate at 3mt 5.6 (2.96) v 8.8(4.71) p=0.235	No blinding Computer generated randomisation

SM=self-management, C=Control, RM= Routine Monitoring, mt=months, D=dyspnoea ,F=fatigue, E=emotion, M=mastery, T=total

Table 2.4 Continued…

Author	Country	n=	Design	Patient characteristics	Intervention	Results	Comments
Bucknall (2012)	UK	464	Parallel group RCT	Age: 69.1(9.3) FEV_1%: 40.5(13.6) SGRQ(T): 70.1(16.4) Male n(%): 170(37) Post hospitalisation	Supervised education, 4 fortnightly home visits for 2months (40 min. each) then every 6 weeks for 10 months	HR admission or death 1.05 (95%CI 0.80 to 1.38) p=0.73 Treatment effect at 12t: SGRQ(T): -4.52(-9.07 to 0.04) p=0.052; HADS-A -1.06(-2.08 to -0.03) p=0.044 No change HADS-D or CSES	Blinded assessment Computer generated randomisation by minimisation <61% response rate on questionnaires
Effing (2011)	Netherlands	159	2 by 2 factorial RCT	(SM) (C) Age: 62.9(8.1) 63.9 (7.8) FEV_1: 1.43(0.54) 1.40(0.53) ISWT: 388(164.5) 341(152.4) CRQ-D: 4.40(1.44) 4.52(1.38) Male %: 58.4 57.9 Stable	Supervised exercise and education 3x week for 6mt 2x week for 5mt Small groups	Treatment effect at 12mt: ISWT 35.1m (8.4-61.8), no p value ESWT 145.8 (-26.2-317.8)m, NS CRQ-D 0.32(-0.03 to 0.67),p=0.04	17 withdrew All but 7 opted in for the additional 5 months All patients had 4x weekly 2hr group education
Fan (2012)	USA	426	Multi-centre RCT	(SM) (C) Age: 66.2(8.4) 65.8(8.2) FEV_1: 1.20(0.47) 1.21(0.49) Male n(%) 204(97.6) 209(96.3) COPD hospital admission within prev. 12mt	Supervised education 1x week for 4weeks Phone calls for 12mt Action Plan Written information	Mean fu= 250 days Deaths: 28 (SM) v 10 (C), HR3.00(1.46-6.17), p=0.003 AE treatment delay: 6.4 days (SM) v 7.7 (C), p=0.48	Terminated early due to higher mortality in SM group 97% male

SM=self-management, C=Control, HADS-A=anxiety, HADS-D=depression, D=dyspnoea, CSES=COPD Self-Efficacy Scale

Table 2.4 Continued…

Author	Country	n=	Design	Patient characteristics	Intervention	Results	Comments
Fernandez (2009)	Spain	50	Prospective RCT	(SM) (C) Age: 66(8) 70(5) FEV_1%: 33(10) 38(12) 6MWT: 302(84) 315(104) Severe COPD, using LTOT	Supervised education, 2 sessions (one hour each) Home exercise programme, 1 hr per day, 5 days per week Twice monthly home visits for 2 months, once monthly for 9 months	Change at 12mt (SM) v (C): 6MWT 79m(p=0.0001) v 13m (ns) SGRQ(T): -14.7(p=0.0001) v -2.5 (ns)	No power calculation Randomisation not reported Blinding not reported No between-group comparisons made
Ghanem (2010)	Egypt	39		(SM) (C) Age: 56.9(11.6) 56.4(9.03) FEV_1: 0.80(0.35) 0.83(0.52) Recruited upon hospital discharge with AE	Supervised education and unsupervised exercise Written information 4x 1hr education while an IP	Treatment effect at 2mt: 6MWT: 58.15(11.23), p<0.001 CRQ(D): 5.5(3.0 to 9.0), p=0.003 (F): 5.3(1.9 to 9.8), p=0.004 (E): 8.7(2.5 to 15.0), p=0.008	Assessor not blinded Not powered to detect change in HRQoL Groups uneven at baseline (n=25 v n=14 for SM and C)

SM=self-management, C=Control, mt=months, D=dyspnoea , F=fatigue, E=emotion, T=total

Table 2.4 Continued…

Author	Country	n=	Design	Patient characteristics	Intervention	Results	Comments
Khdour (2009)	UK	173	RCT longitudinal, prospective clinical trial	(SM) (C) Age: 65.6(10.1) 67.3(9.2) FEV_1: 0.95(0.48) 1.10(0.50) Male %: 43.7 44.2 SGRQ: 63.6 64.2 (59.8 to 66.6) (60.5 to 67.9) Stable, outpatient	Unsupervised education and exercise Written information Supported by pharmacist using MI Phone contact at 3mt and 9mt Reinforcement in clinic	Treatment effect at 6mt: SGRQ(T): -5.2, p=0.04 (S): -7.8,p=0.01; (A) -1.8, ns; (I)-7.5,p=0.01 Treatment effect at 12m: SGRQ(T): -3.8, p=0.17 (S): -7.5,p=0.04; (A) -1.8, p=0.51; (I)-7.4,p=0.03 Admission for AE 15 (SM) v 34(C) at 6mt, p=0.01 Admission for AE 26 (SM) v 64 (C) at 12mt, p=0.01	Blinding not reported Computer generated randomisation
Maltais (2008)	Canada	252	Non-inferiority RCT Multi-centre	(SM) (PR) Age: 66(9) 66(9) FEV_1: 1.13(0.34) 1.08(0.39) Male %: 57 54 6MWT: 370(89) 368(85) Outpatient clinics	Supervised education and unsupervised exercise Education 2x week, 4 weeks Exercise 3x week (40mins), 8 weeks Phone contact Loaned cycles	Between-group at 3mt: CRQ(D):0.05(-0.21 to 0.29), p=0.74; (F):-0.02(0.24 to 0.20), p=0.85; (E): -0.10(-0.36 to 0.16), p=0.46; (M): -0.03(-0.23 to 0.17), p=0.75 Between-group at 12mt: CRQ(D): 0.16(-0.08 to 0.40), p=0.20; (F): 0.09(-0.14 to 0.34), p=0.41; (E): 0.18(-0.08 to 0.44), p=0.15; (M): 0.08(-0.12 to 0.28), p=0.45 Change 6MWT at 12mt (SM) v (C): -3(-15 to 10) v -5(-12 to 21)	Assessment not blinded Computer generated randomisation

SM=self-management, C=Control, PR= Pulmonary Rehabilitation mt=months, D=dyspnoea, F=fatigue, E=emotion, M=mastery, T=total, S=symptoms, I=impact, A=Activity

Table 2.4 Continued…

Author	Country	n=	Design	Patient characteristics	Intervention	Results	Comments
McGeoch (2006)	New Zealand	159	RCT	(SM) (C) Age: 69.8(11.6) 72.1(9.9) FEV_1: 1.4(0.6) 1.4(0.5) Male %: 52 67 SGRQ: 43.5(18.8) 36.8(17.6) HADSA: 6.2(4.2) 5.3(3.6) HADSD: 4.6(3.7) 4.1(2.9) Stable, from GP registers	Action Plan Introduced by PN over 1hr.	Change at 12mt (SM)v(C): SGRQ(T): 1.7(1.6) v -0.43(1.6), p=0.58 (S): -7.8(2.2) v -5.5 (2.7), p=0.52 (A):1.1(1.8) v -0.92(2.3), p=0.47 (I):-2.1(1.6) v 1.2(1.7), p=0.17 HADSA:-0.15(0.7)v 0.01(0.03), p=0.87 HADSD:-0.29(0.29)v -0.04(0.32), p=0.57	Assessor not blinded Randomisation not reported
Mendes (2010)	Brazil	117	RCT, 3 group	Age: 69.2(8.7) FEV_1%:46.5(22.0) Male (%): 76.5 Stable, private OP clinics	Supervised education and unsupervised exercise 1x group education Home training 3x week for 3m Phone contact	Change 6MWT at 3mt: 73.2(50.2), p<0.05 within-group Compared with OP-PR, change6MWT p=0.44 Withdrawals: n=7 (SM) v n=19(OP-PR)	Did not report change between SM and control Computer generated randomisation Blinding not reported

SM=self-management, C=Control, OP-PR= outpatient pulmonary rehabilitation, T=total, S=symptoms, I=impact, A=Activity, HADSA=anxiety, HADSD=depression

Table 2.4 Continued…

Author	Country	n=	Design	Patient characteristics	Intervention	Results	Comments
Monninkhof (2003)	Netherlands	248	2 by 2 RCT	Age: 65 (7) FEV_1%: 57 (15) Male (n): 169 (SM) (C) SGRQ: 37.2(1.6) 38.1(1.5) 6MWT: 428(91) 442(83) Stable, OP Clinic	Supervised exercise and education Education – 5x 2h group Exercise – 1 or 2x week for 2 years Written info, AP	Treatment effect at 12mt: SQRQ(T) -0.6(-2.8 to1.7), ns; (S)1.1(-2.5 to 4.8), ns; (A) -0.2(-3.2 to 2.8), ns; (I)-1.4(-3.9 to 1.1), ns 6MWT: -13(7)m (SM) vs. -2(5)m (C), ns	Assessment not blinded Block randomisation by sealed envelopes
Moore (2009)	UK	27	Pilot, RCT	(SM) (C) Age: 70(13) 70.5 (57.5-78.15) FEV_1: 0.94 (0.66-1.17) 0.96 (0.77-1.31) Male n: 6 4 ISWT: 110(30-270) 160(45-85) CRQ-D: 3.3(1.8-4.1) 2.7(2-4.8)	Unsupervised exercise and education Education – written information Exercise – DVD led, 4x week (30mins) for 6 weeks One consultation with PT	Change at 7 weeks (SM) v (C): ISWT:45 v -15, p=0.013; CRQ(D): 0.5 v -0.1, p=0.042; (F): 1.7 v 0.0, p=0.012; (M): 0.6 v 0.8, p=0.253	Assessment not blinded Randomisation conducted via sealed envelopes

SM=self-management, C=Control, T=total, S=symptoms, I=impact, A=Activity, PT=physiotherapist

Table 2.4 Continued…

Author	Country	n=	Design	Patient characteristics	Intervention	Results	Comments
Ninot (2010)	France	45	RCT	(SM) (C) Age: 65(59.24) 61(56.65) FEV_1: 1.69 1.52 (1.17-2.01) (1.06-1.85) Male n: 18 14 SGRQ: 44(26.56) 41(27.51) 6MWT: 450 397 (385-505) (360-470)	Supervised education and exercise 2x weekly, 4 weeks Phone contact	Change at 12mt (SM)v (C): ISWT 30(5to8)m v 12.5 (15to48)m, p=0.15 SGRQ(T): -7.6(-18to-1) v -4.7(-11 to 4), p=0.15; (S): -7(-19 to 1) v 3.7(-18 to 18), p=0.02; (A):-6.7(-16 to -5) v -6.7(-13 to o), p=0.61; (I): -6.3(-24 to o) v -5.6(-9 to 9), p=0.18	Assessment not blinded Randomisation provided by statistician via fax Underpowered on SGRQ
Watson (1997)	New Zealand	69	RCT	(SM) (C) Age: 68(10) 67(8) FEV_1%: 37(14) 36(16) Male %: 62 67 SGRQ(T): 43(15) 39(16)	PN introduced AP <60 mins duration	Change at 6mt (SM) v (C): SGRQ(T): -4 v 0, ns; (A); -2 v 1, ns; (I): -3 v 1, ns; (S): -8 v -2, ns	Blinding not reported Randomisation not reported

SM=self-management, C=Control, T=total, S=symptoms, I=impact, A=Activity

Education with supervised exercise programmes.

There are four studies in this review which have been defined by the authors as self-management, and include a programme of education alongside supervised exercise training.

One of the earlier studies evaluating the effects of a self-management programme for COPD was a Dutch study, COPE-I (Monninkhof 2003). This was an RCT design which recruited and randomised 248 participants [mean (SD) age 65(7) years; FEV_1 % predicted 57(15); baseline 6MWT 428(91) metres and 442(83) metres for self-management (SM) and usual care (UC) respectively]. Branded as self-management, the intervention included five separate two-hour education sessions in small groups over the period of four months as well as one or two exercise training in small groups, weekly, for two years. Training consisted of cycling, walking, upper limb and lower limb strength training under supervision of a physiotherapist and was regularly adjusted with the patient to achieve goals. Education addressed medical, role and emotional management tasks and provided patients with knowledge and skills.

Despite a complex and comprehensive intervention, the study failed to detect any difference between intervention and usual care groups in HRQoL, exercise capacity, symptoms, exacerbation frequency or self-confidence. The authors suggest that as the control group were medically optimised, shown inhaler technique and provided with smoking cessation which perhaps diminished the room for difference between groups. Additionally, they might

be considered quite a 'well' group of patients with high baseline scores in HRQoL [mean (SD) SGRQ Total 37.2 (1.6)] and exercise performance [mean (SD) 6MWD 428 (91) metres]. This may have created a ceiling effect whereby there was limited scope for improvement. Furthermore, this sample were relatively mild in terms of airflow obstruction, (FEV_1 1.71 litres), and perhaps the patients were 'too well' for such a comprehensive intervention.

More recently the effectiveness of a modified intervention, COPE-II, has been published (Effing et al. 2011). This was another Dutch study which recruited and randomised 159 participants [for SM and UC respectively, mean (SD) age 62.9(8.1), 63.9(7.8) years; FEV_1 1.43(0.54), 1.40(0.53) litres; baseline ISWT 388(164.5), 341(152.4) metres]. The education was reduced to four sessions, but was supported with written material and phone calls at four, 13 and 26 weeks. The content of the exercise training was similar to that described in COPE I, however it was carried out three times per week for the first six months and then twice weekly for an optional five months with one session per week being carried out at home.

At the end of the study there were statistically significant between-group differences in the primary outcome of ISWT of mean (95% CI) 35.1 (8.4 to 61.8) m, and CRQ dyspnoea 0.32 (-0.03 to 0.67), p =0.04 at 12 months, although neither of these differences breached the relative MCIDs. A significant difference of the number of steps [mean (95% CI) 1,190 (255 to 2125)] measured by a pedometer was found in favour of the intervention at 12 months. The usual care group in this study had a significant amount of

intervention, receiving the education, written information, phone calls, smoking cessation advice if needed and being allowed to access their normal physiotherapy exercise if it was part of their usual care. Although the authors argue this is likely to diminish the between-group effect, the between-group difference that was observed on the ISWT was largely accommodated for by the 24m decline in the usual care group rather than the 11m improvement in the self-management group. Even at an interim assessment at seven months there was only a 12m improvement in the intervention group, which after supervised exercise three times per week for six months, might be considered a small improvement.

An optimal training threshold for individuals with COPD has been described at around 60-85% (Nici et al. 2006; Revill et al. 1999). Neither of the COPE studies described the intensity of training during the exercise component of their programmes, therefore it is not possible to evaluate whether training was optimally prescribed in these studies. It is also unfortunate that short-term measurements were not taken, such as at six or12 weeks from baseline as it has been shown in the literature that physical gains made in the short-term may diminish by 12 months (Bourbeau et al. 2003; Maltais et al. 2008). These studies, therefore, may have missed data collection when gains were at the optimum.

Boxall et al. (2005) conducted an RCT in 60 people with COPD [mean (SD) age 77.6 (7.6), 75.8 (8.1) yrs, FEV_1 0.79 (0.33), 0.89 (0.37) litres for SM and UC respectively] to test a self-management programme. It involved nine one-

to-one home visits, with supervised education and exercise. Short-term outcome measures (12 weeks) were taken immediately post intervention, and documented a 34.9m change in exercise performance. Other significant between-group outcomes were HRQoL on SGRQ total and impact domains, which were also clinically significant. It was not possible to blind researchers or participants in this study and it was underpowered with analysis performed on only 60 participants, therefore results must be treated cautiously. It is, however, interesting that although less intensive than the COPE interventions the programme described in this study yielded greater benefits. Participants in this study were older, more severe and had a lower 6MWT distance at baseline. This may explain why Boxall et al. showed greater benefits than COPE, as those who are worse at baseline have the most to gain.

Ninot et al. (2011) conducted an RCT in France, and recruited and randomised 45 people with COPD [mean (SD) age 65 (59.24), 61 (56.65) years; mean (95% CI) FEV_1 1.69(1.17-2.010, 1.52(1.06-1.85) litres; baseline 6MWT 450(385-505), 397(360-470) metres for SM and UC respectively]. Outpatient sessions of supervised education and exercise in small groups were provided twice weekly for four weeks. Exercise was based on a cycling programme but no details with regard to prescription were described. The study demonstrated non-significant between-group difference of 17.5m (p=0.15) on 6MWD, and clinically significant improvements in all four domains of the SGRQ at 12 months. This study, however, only included 45 participants which resulted in uneven groups at baseline, and data was not normally distributed. Although the results on the SGRQ are significantly improved, the

study was not adequately powered to detect this change. A major limitation of this study is that no short-term outcome measures were performed at the end of the intervention period (four weeks). It is not possible to establish, therefore, whether the lack of change at 12 months is because the intervention failed to intervene, or whether a short-term effect was not maintained during the 12 month follow-up.

Of these four studies, three demonstrated some impact on HRQoL and two demonstrated there were small gains in walking performance, which were statistically but not necessarily clinically significant. It is surprising that better results were not seen, given these studies included supervised exercise and education to a level which was comparable or more than that of many pulmonary rehabilitation programmes. With the exception of the study by Boxall et al. (2005), all others included patients with high FEV_1 and baseline exercise capacity. The failure to observe larger improvements in these studies may be because they were relatively 'well' patients at baseline, there was less room for improvement and a ceiling effect on the tests occurred. Another possibility, however, is that the interventions in these studies were highly supervised and may have been too onerous for the well functioning patients. The COPE studies both required weekly attendance at hospital for up to a year (Effing et al. 2011; Monninkhof et al. 2003), which may have created dependence upon the healthcare team rather than fostering independence and establishing self-management skills. It is worth considering that the level of intervention should be appropriate for the severity of the patients, and

perhaps heavily supervised interventions for quite mild patients may not be the best way to direct resources.

Education with unsupervised exercise

Seven studies were found from the literature search which evaluated programmes of education with unsupervised exercise training. One of the most highly cited of these is the 'Living Well with COPD' programme (Bourbeau et al. 2003). It was a multi-centre RCT in Canada, and recruited patients who had been admitted to hospital due to COPD within the previous 12 months. 191 individuals with COPD [mean (SD) age; 69.4(6.5), 69.6(7.4) years; FEV_1 1.00(0.33), 0.98(0.31) litres; baseline 6MWT 282(91), 280(90) metres for SM and UC respectively] were randomised to either usual care or home-based self-management. The programme consisted of seven or eight individual home visits (one hour each) by a healthcare professional to conduct a comprehensive educational programme which addressed knowledge, respiratory skills, action planning for exacerbations and emotional support. Exercise was introduced at home and individuals were instructed to walk, cycle and climb stairs three times per week for 30-45 minutes per session.

No significant between-group differences were found on the 6MWT. There were clinically significant between-group differences in the impact and total scores of the SGRQ at four months. Only the impact score remained clinically significant at 12 months ($p=0.05$). In the 12 months from baseline there was a 39.8% reduction in admission from acute exacerbation, 51.7% reduction in admission for reasons other than exacerbation and a 41% reduction in

emergency department visits for exacerbation in the self-management group, compared with usual care. This was evaluated again after the second year and significant between-group differences remained (Gadoury et al. 2005). This is in contrast to results found from the study by Boxall et al. (2005) who found no significant difference on hospital admission. This may be because Bourbeau and colleagues only included patients who had had at least one hospitalisation in the preceding year, and as such they recruited a group of patients who were more likely to admit to hospital. It is likely that there was a greater occurrence rate of exacerbations in this group than those in the other studies. If the occurrence rate of an event is low, it can be difficult to find a difference and usually large numbers are needed. It is likely therefore that the study by Boxall et al., with just 60 patients, was insufficiently powered to detect a change in hospitalisation.

In 2008 the 'Living Well with COPD' programme was evaluated again, with modifications, against conventional outpatient pulmonary rehabilitation (Maltais et al. 2008). This time the education was delivered in small groups, twice weekly for four weeks. The self-management groups were loaned exercise cycles for three months and were prescribed a training intensity of 60% of their maximum that they achieved on a baseline cycle test, and were instructed to train for 40 minutes three times per week for eight weeks. A low intensity and long duration was deliberately prescribed so as to avoid severe dyspnoea on unsupervised exercise. Outcomes were performed at three and 12 months. 252 people with COPD were recruited [mean (SD) age 66 (9), 66 (9) years; FEV_1 1.13 (0.34), 1.08 (0.39) litres; baseline 6MWT 370 (89), 368

(85) metres for SM and pulmonary rehabilitation (PR) groups respectively]. Again, HRQoL was found to improve clinically significantly in all four domains of the SGRQ at three months, and all but the activity domain remained so at 12 months. CRQ dyspnoea also exceeded the MCID at 12 months. There was no improvement in 6MWD, however a statistically significant improvement in cycling endurance time was observed. A key finding from this study was that the self-management home-exercise programme was not inferior to the outpatient supervised exercise programme in terms of HRQoL. While the 'Living Well with COPD' programme is detailed in its approach to promoting self-management, a concern with the delivery method is that participants were loaned exercise bikes which were then withdrawn and patients were encouraged to buy their own. Firstly this increases the expense and logistics of the programme, which restricts its implementation in the UK. It is may also have significant implications for exercise maintenance if participants are loaned equipment and then expected to buy their own.

Very few studies which have been discussed have demonstrated significant impact on exercise performance, and none have convincingly evidenced improvements in walking exceeding the MCID. There are, however, a number of studies which have included unsupervised exercise which have shown more impressive results. Mendes et al. (2010), Moore et al. (2009), Fernandez et al. (2009), and Ghanem et al. (2010) all conducted studies which included an educational programme and a home-based, unsupervised training programme and found improvements in exercise tolerance which were either statistically significant or exceeded the MCID.

Mendes et al. (2010) conducted a three arm RCT in Brazil in 117 patients [mean (SD) age 69.2(8.7) years; FEV_1 % predicted 46.5 (22.0)]. Patients were randomised to either usual care, pulmonary rehabilitation or a home-based self-management programme. Patients who received the self-management programme were advised to complete 30 minutes of walking at 60-80% maximal heart rate achieved on the 6MWT three times per week. They also received a group-based single education session and telephone support. After 12 weeks a 73m improvement in 6MWD was documented in the self-management group, however, the authors did not report how this compared with the usual care group. There were seven drop outs in the self-management group compared with 19 in the rehabilitation group, which the authors suggest means self-management may be more acceptable for some patients.

Moore and colleagues (2009) tested a novel DVD approach to home-based exercise programme, and although exercise was chair-based, patients were instructed to use the Borg breathlessness scale to train to a symptom limited intensity. Education was provided in written format from British Lung Foundation material. The study was based in the UK, and included a small sample of 27 [mean (SD or 95% CI) 70 (13), 70.5 (57.5-78.15) years; FEV_1 0.94 (0.66-1.17) litres, 0.96 (0.77-1.31); baseline ISWT 111 (30-270), 160 (45-85) metres for SM and UC]. A 60m between-group difference on the ISWT was observed in the self-management group vs. usual care at six weeks. Statistically significant between-group differences were seen on the dyspnoea, fatigue and emotion domains of the CRQ. This was a small study,

and the non-normally distributed data suggests this may not be a representative sample.

In the study by Fernandez et al. (2009) participants were advised to exercise for one hour per day, five days per week. Training included upper and lower limb resistance training and a walking programme prescribed at 90% of the peak velocity achieved on the 6MWT. The educational programme was conducted through twice monthly home visits for two months and once monthly visits for nine months. The study was conducted in Spain and recruited 50 people with COPD [mean (SD) 67 (8) years; FEV_1 % predicted 33(10), 38 (12) litres, baseline 6MWT 302 (84), 315 (104) metres for SM and UC respectively]. A between-group difference of 66m on 6MWT after 12 months was documented, and clinically significant improvements in HRQoL were observed in all four domains of the SGRQ. No power calculation was reported, recruitment and randomisation procedure are not clear and it does not explain why there were 27 people in the self-management group and 14 in the usual care.

Ghanem et al. (2010) conducted an RCT in Egypt. During hospitalisation for an exacerbation of COPD, 39 people with COPD were recruited and randomised [mean (SD) age 56.9 (11.6), 56.4 (9.03) years; FEV_1 0.80 (0.35), 0.83 (0.52) litres for SM and UC respectively]. It failed to describe any detail with regard to the prescription of the exercise training, other than that patients in the self-management arm were advised to carry out cycling, walking, respiratory muscle training and strength training every day at home. The

education programme was provided during the hospital stay during four one-hour sessions. Significant between-group differences were found after two months on the 6MWT of 58.15 (11.23) metres, p<0.001, CRQ dyspnoea of 5.5 (3.0 to 9.0), p=0.003, fatigue 5.3 (1.9 to 9.8) and emotion 8.7 (2.5 to 15.0). Despite being a young group they had a low FEV_1, however this may reflect the fact that these patients were recruited in hospital.

These four studies are the only programmes which have incorporated education with unsupervised exercise and shown a positive impact on exercise performance. In comparison with the studies of supervised exercise discussed earlier, the participants in these studies were more severe, in terms of baseline function and FEV_1, therefore better improvements in exercise capacity may have been observed as these patients had more to gain.

There are several issues with the quality of these studies. With the exception of the study by Mendes et al. (2010), all of these trials had small samples [n=50, n=39, n=27 for Fernandez et al. (2009), Ghanem et al. (2010) and Moore et al. (2009) respectively]. Having not reported a power calculation, it is likely that these studies are insufficiently powered. And while Mendes et al. did report a significant within-group change in exercise performance in the self-management group, they did not report a between-group comparison with the control group. Additionally, none of these studies reported using a blinded assessor, or using an intention to treat approach in the analysis. Both Fernandez et al (2009) and Ghanem et al. (2010) did not report how participants were recruited and both studies had uneven numbers in the self-

management and usual care groups at baseline [self-management vs. usual care n=30 and n=20 (Fernandez et al.), n=25 and n=14 (Ghanem et al.)], which raises concerns about how randomisation was conducted.

Despite the lack of rigour and lack of power in these studies, they suggest that exercise performance can be improved in people with COPD who follow an unsupervised programme of training. This is an important finding, but must be substantiated with more high quality research.

Another study which included an unsupervised exercise programme alongside education to promote self-management was that by Khdour et al. (2009), although this study did not measure exercise capacity. The study was based in the UK and recruited 173 participants with COPD [mean (SD) age 65.6 (10.1), 67.3 (9.2) years; FEV_1 0.95 (0.48), 1.10 (0.50) litres for SM and UC respectively]. The intervention was pharmacist-led, and introduced participants individually to the programme in a one-hour session, which included knowledge on COPD and skills in inhalation technique, symptom management, relaxation and chest clearance. This was supported with written information, phone calls and re-enforced at clinical appointments. Exercise training was only advised, not prescribed. Interestingly this is one of the few studies that have reported using motivational interviewing as a technique to support the delivery of the programme. HRQoL significantly improved on the SGRQ at six months but had declined at 12 months [SGRQ-Total treatment effect at six months = -5.2 (p=0.04) and at 12 months= -3.8 (p=0.17)]. Supporting findings by Bourbeau et al. (2003), a 50% decrease in emergency

department visits, 59% decrease in hospitalisation and a 39% decrease in unscheduled GP visits was observed in the intervention group compared with usual care. Similar to the study by Bourbeau et al. (2003), this was a more severe group of patients. Although the study was not powered to detect change in healthcare utilisation and was not blinded, this is an interesting finding given that the level of additional support that the intervention required was a one-hour consultation, two phone calls and written information. This is considerably less intervention than the 'Living Well with COPD' programme, which achieved similar results, but required eight one-to-one home visits. This suggests that a 'light touch' approach is not only feasible, but may deliver similar results, in a similar population, compared with a more supervised programme.

Self-management education – no formal exercise

There are a number of programmes under the label of self-management with the primary aim of helping patients to self-manage their exacerbations. These approaches have usually focused on education specifically tailored around the exacerbation, often with the aim of prompting identification and early treatment of an exacerbation to minimise its impact and reduce the risk of hospitalisation.

Two of these five studies evaluated the impact of a simple action plan. An action plan is a set of written instructions which aims to equip the patient with knowledge of how to identify the symptoms of an exacerbation, what course of treatment to take and to initiate it early. Watson et al. (1997) recruited and

randomised 69 participants with COPD in New Zealand [mean (SD) age 68(10), 67(8) years; FEV_1 % predicted 37(14), 36(16) litres for SM and UC respectively]. Participants in the self-management arm were introduced to the action plan by a practice nurse. No further advice or support was given. No significant between-group differences in HRQoL were observed [mean change at six months SGRQ total -4 vs. 0, activity -2 vs. 1, impact -3 vs. 1 and symptoms -8 vs. -2].

A similar study was conducted by McGeoch et al. (2006), also in New Zealand, with larger numbers. 159 patients were recruited and randomised [mean (SD) age 69.8(11.6), 72.1(9.9) years; FEV_1 1.4 (0.6), 1.40 (0.5) litres for SM and UC respectively]. The intervention was also an introduction to the action plan without further support. Changes in HRQoL, anxiety or depression were neither statistically nor clinically significant [mean (SD) change, for SM and UC respectively, SGRQ total 1.7(1.6) vs. 0.43 (1.6), p=0.58; HADS-A -0.15(0.7) vs. 0.01(0.03), p=0.87; HADS-D -0.29 (0.29) vs. 0.04 (0.32), p=0.57].

A Cochrane Review of the use of action plans without any formal patient education included a further three studies, and concluded that the use of action plans in isolation could not be recommended as there was no evidence of any benefit in either HRQoL or healthcare utilisation (Walters et al. 2010). While there may still be a place for action plans which are integrated into a broader self-management approach, used alone they appear to offer little clinical benefit.

One study published recently, embedded an action plan within a programme of patient education, which was based on the 'Living Well with COPD' course. Bischoff and colleagues (2012) recruited from primary care in the Netherlands. It was a three-group RCT, in which patients were randomised to self-management, routine monitoring or usual care. 165 people with COPD were recruited and randomised [mean (SD) age 66(12), 64(10), 66(8) years; FEV_1 % predicted 66(17), 67(18), 63(14) for SM, UC and routine monitoring respectively]. Participants in the self-management group received a Dutch version of the programme, which included written modules and an action plan. It was delivered by the practice nurse in two to four one-hour sessions, although the precise number of sessions varied. The primary outcome was the CRQ total and there was no significant treatment effect at 24 months between self-management and usual care [mean change (95% CI) -0.22 (-0.49 to 0.042]. There were no significant effects in any of the CRQ domains or in the self-efficacy scale at either six or 24 months. In the second year of follow-up more exacerbations were managed with bronchodilator use [odds ratio (95%CI) 2.81 (1.16 to 6.82)] or with prednisalone, antibiotics or both [3.98 (1.10 to 15.58)] and there was also a tendency for more exacerbations to be reported in the self-management group compared with usual care.

The lack of short-term follow-up in this study means it is difficult to identify whether the intervention failed to intervene, or whether improvements were made but not maintained. A short-term assessment is important to establish this. It is interesting, however, that despite being modelled on the same programme that was used by Bourbeau et al. (2003) and Maltais et al. (2008),

which documented significant improvements in HRQoL, this study showed little clinical impact. This may be because the patients in the Bischoff et al. study were recruited from primary care, and therefore may be a 'better' group of patients. Their baseline HRQoL scores were high, which may have created a ceiling effect. Another important difference is the absence of the exercise component of the programme. The authors have not explained why this element of the programme was withdrawn, although it may be because it was delivered by practice nurses in primary care. It is, however, possible that improvements in exercise capacity may be an important factor in minimising the impact of the disease symptoms and therefore improving quality of life.

There have been a further two studies which evaluated the impact of a self-management education intervention, which did not include any exercise. These final two studies aimed to specifically target patients who had previously been admitted to hospital due to an exacerbation of COPD. Firstly, the Glasgow Supported Self-management Trial (GSuST) was published last year (Bucknall et al. 2012). It recruited and randomised 464 people with COPD [mean (SD) age 69.1(9.3) years; FEV_1% predicted 40.5(13.6); baseline SGRQ total 70.1(16.4)]. Those randomised to self-management received four forty-minute one-to-one sessions from the study nurse during the first two months, followed by home-visits every six weeks for another 10 months. The self-management education was adapted from the 'Living Well with COPD' programme, however was specifically adapted to focus on exacerbation management. The primary endpoint was time to re-admission or death. 48% of the self-management group and 47% of the usual care group

reached the primary endpoint within 12 months. There was no significant difference between-groups in risk of re-admission or death [Hazard ratio (95% CI) 1.05(0.80 to 1.37) p=0.73]. There was a low response-rate on the questionnaire data, with baseline and at least one follow-up only available for 61% of people. Of the data that was returned there was a significant treatment effect on some domains of HRQoL and anxiety on the HADS [treatment effect (95% CI) SGRQ-impact -6.89 (-12.40 to -1.39), p=0.015; HADS-A -1.06 (-2.08 to -0.03), p=0.044]. There was no impact on other domains of the SGRQ, depression or self-efficacy.

The study team attempted to identify 'successful self-managers' in this trial as those who initiated rescue medication appropriately following the onset of an exacerbation. A sub-group analysis was performed on this group, and there was a significant reduction in having more than one hospitalisation for COPD in the 'successful self-manager' group [hazard ratio (95%CI) 0.44 (0.25-0.76) p=0.003]. This is the first study to try to identify a target group in this way, and is important for future studies to consider who might be most appropriate for self-management. We should be cautious, however, to limit the 'success' of self-management to initiation of rescue medication. Other studies have documented improved medication adherence, however, this has not necessarily translated into any other markers of improved health status or reduced healthcare utilisation (Walters et al. 2010).

The second study which targeted people following hospitalisation was an American study in a veteran affairs institute (Fan et al. 2012) 426 people with

COPD were recruited and randomised [mean (SD) age 66.2(8.4), 65.8(8.2) years; FEV_1 1.20(0.47), 1.21(0.49) litres for SM and UC respectively]. Participants in the self-management group received a written action plan, had supervised education once a week for four weeks and received regular telephone contact for 12 months. The study aimed to recruit 960 patients, however, it was terminated prematurely because of safety concerns due to higher mortality in the self-management arm [deaths=28 vs. 10 for self-management v usual care respectively, hazard ratio (95% CI) 3.00 (1.46 to 6.17) p=0.003]. Among those who did complete the study there were no between-group differences in HRQoL. Furthermore, there was no between-group difference in the delay between exacerbation onset and initiation of treatment [mean 6.4 days vs. 7.7 days for self-management and control, (p=0.48)], suggesting that the intervention had failed to intervene in the way in which it was intended.

Despite best efforts, no clear reason for the difference in mortality was found. It could be argued that the study was underpowered as they did not meet the power calculation, and had the study achieved statistical power, this difference may not have existed. Additionally, it should be noted that as these patients had recently been hospitalised, the mortality rate of 13% in the intervention group might not actually be considered to be beyond what is expected for this population.

Both the studies by Bucknall et al. (2012) and Fan et al. (2012) suggest that the timing of self-management may be important. A recent study which

evaluated the natural progression of COPD indicated that the first hospitalisation signals a progressive decline, and that subsequent exacerbations become more frequent and regular (Suissa, Dell'Aniello, and Ernst 2012). Initiating self-management support following hospitalisation may be too late in the disease process to have a significant impact on clinical outcomes. Self-management is a subtle intervention, and behaviour change may be more difficult to achieve once the disease is further advanced.

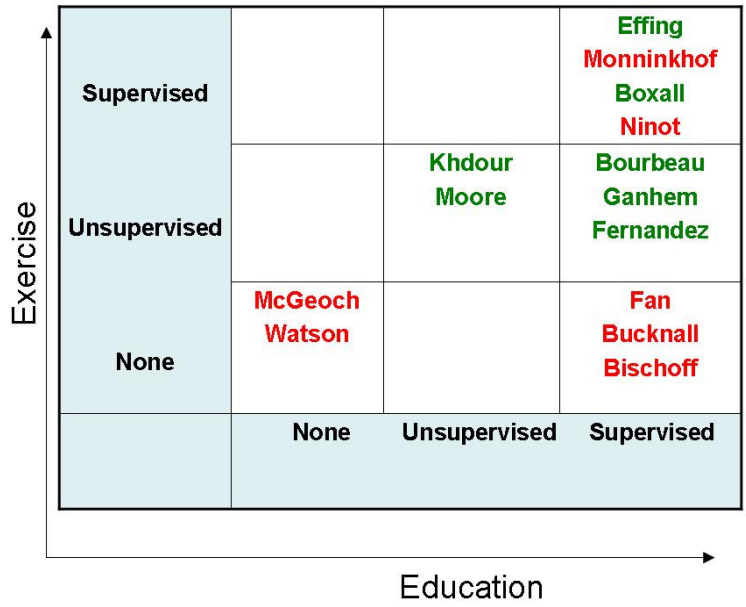
On the whole, studies which have included written information without any formal exercise component have had very limited success. While some of these studies have recruited quite 'well' patients and may have experienced a ceiling effect, others have recruited more severe participants and still experienced little improvement. These studies have included a range of education programmes, from something as basic as an action plan through to one-to-one home visits for a year, and yet this seems to have little impact on the clinical effectiveness. The lack of an exercise programme may be important in understanding why these programmes have not had better outcomes. It seems intuitive that in order to for HRQoL to improve, an individual must experience an alleviation of either physical or emotional symptoms. Alleviation of the symptoms of dyspnoea, fatigue and exercise intolerance is largely achieved through improved exercise capacity. It seems pivotal, therefore, that exercise which is an important health behaviour, should be included within a self-management programme.

2.5.2 Summary of self-management programmes for COPD

This review of the literature on self-management for COPD is in keeping with the Cochrane Review of self-management which concluded that there is heterogeneity in the nature and content of the interventions, the outcome measures used and the time to follow-up (Effing et al. 2007). There are several key findings from the review which will be summarised below.

The level of supervision required by a healthcare professional on a self-management programme is important to consider in order to ensure safety and clinical effectiveness, but there are also financial and organisational implications of the level of support required. While it might be assumed that more support would lead to better outcomes, the findings from this review do not confirm this. Figure 2.6 and 2.7 represent all the studies included in this review on two grids. The x-axis represents the level of supervision provided in the education aspect of the programme while the y-axis represents the level of supervision provided in the exercise component. Names in red represent a statistically negative trial outcome and those in green a statistically positive trial outcome. Figure 2.6 shows the outcome on HRQoL and figure 2.7 shows the outcome on exercise performance.

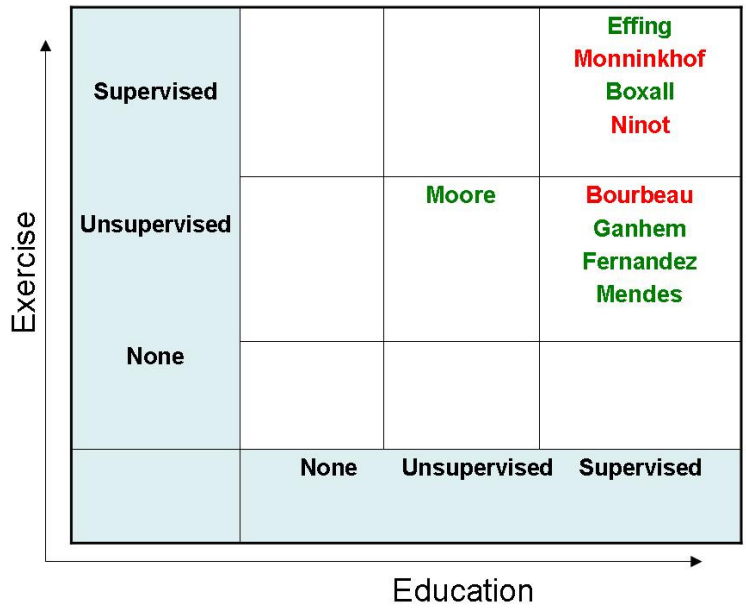
Figure 2.6 Grid of study outcomes on HRQoL



RED=
No impact

GREEN=
Significant impact

Figure 2.7 Grid of study outcomes on exercise performance



RED=
No impact

GREEN=
Significant impact

These figures illustrate that higher levels of supervision does not necessarily lead to better outcomes. Unsupervised approaches, such as that used by Khdour et al. (2009), had a better impact that more supervised programmes, such as Monninkhof and Ninot (Monninkhof 2003; Ninot et al. 2011). This may, in part, be due to disease severity which was worse in the Khdour et al. (2009) study which may allow for greater improvements. It may also be important, however, to ensure that the treatment approach is appropriate for the severity of the patients. For instance, Monninkhof et al. (2003) recruited mild patients to a highly structured programme, which may have been too restrictive for self-management skills to develop.

Several studies included unsupervised exercise training, and demonstrated clinical effectiveness, in terms of HRQoL, exercise performance and reduced healthcare utilisation (Fernandez et al. 2009;Ghanem et al. 2010;Khdour et al. 2009;Mendes et al. 2010; Moore et al. 2009). This suggests these programmes were effective in provoking changes in health behaviour. Improved exercise performance following unsupervised exercise training is an important finding, as supervised exercise training incurs significant financial and organisational costs. There is, however, a need for better quality research in this area which is adequately powered.

What this review has highlighted, and can be seen in figure 2.6, is that some form of exercise component is important within a self-management programme in order to bring about changes in HRQoL. As previously discussed, exercise may be a crucial vehicle by which physiological and

emotional changes occur, which is important in bringing about changes in HRQoL.

This review has also offered some insight in the importance of timing of self-management provision within the course of the disease. The studies by Fan et al. (2012) and Bucknall et al. (2012) suggest that initiating self-management support once the disease is well established enough that the patient is being hospitalised for their condition may be too late to have any strong clinical benefit. This may, however, depend upon the nature of the intervention, as Bourbeau et al. (2003) also recruited people who had previously been hospitalised and did observe a positive impact. The papers in this review which have studied less severe patients, have on the whole, shown less clinical effectiveness than trials which have studied patients at the more severe end of the spectrum. As discussed previously, this may be due to a ceiling effect insofar that the 'well' patients have less room to improve. This does not mean, however, that self-management support is not effective in these people. Intuitively, self-management support aimed at improving health behaviours provided earlier within the course of the disease may have more of a preventative approach. It is possible, therefore, it may just take longer to see the benefits of self-management in these less sever patients.

Some of the self-management programmes described are similar in structure and content to that of pulmonary rehabilitation in the UK. This may be in part due to mixed interpretations of 'self-management' and different systems of healthcare which operate various programmes of rehabilitation around the

globe. It is clear from the literature that there are different levels of self-management support, and it may be that these can be applied in a tiered process. In order to move our understanding of self-management forward it is important to differentiate between the various skills and processes which are involved. The work reviewed so far has culminated in the production of a model of ‘A spectrum of self-management support’ (Wagg 2012).

Figure 2.8 A spectrum of self-management support

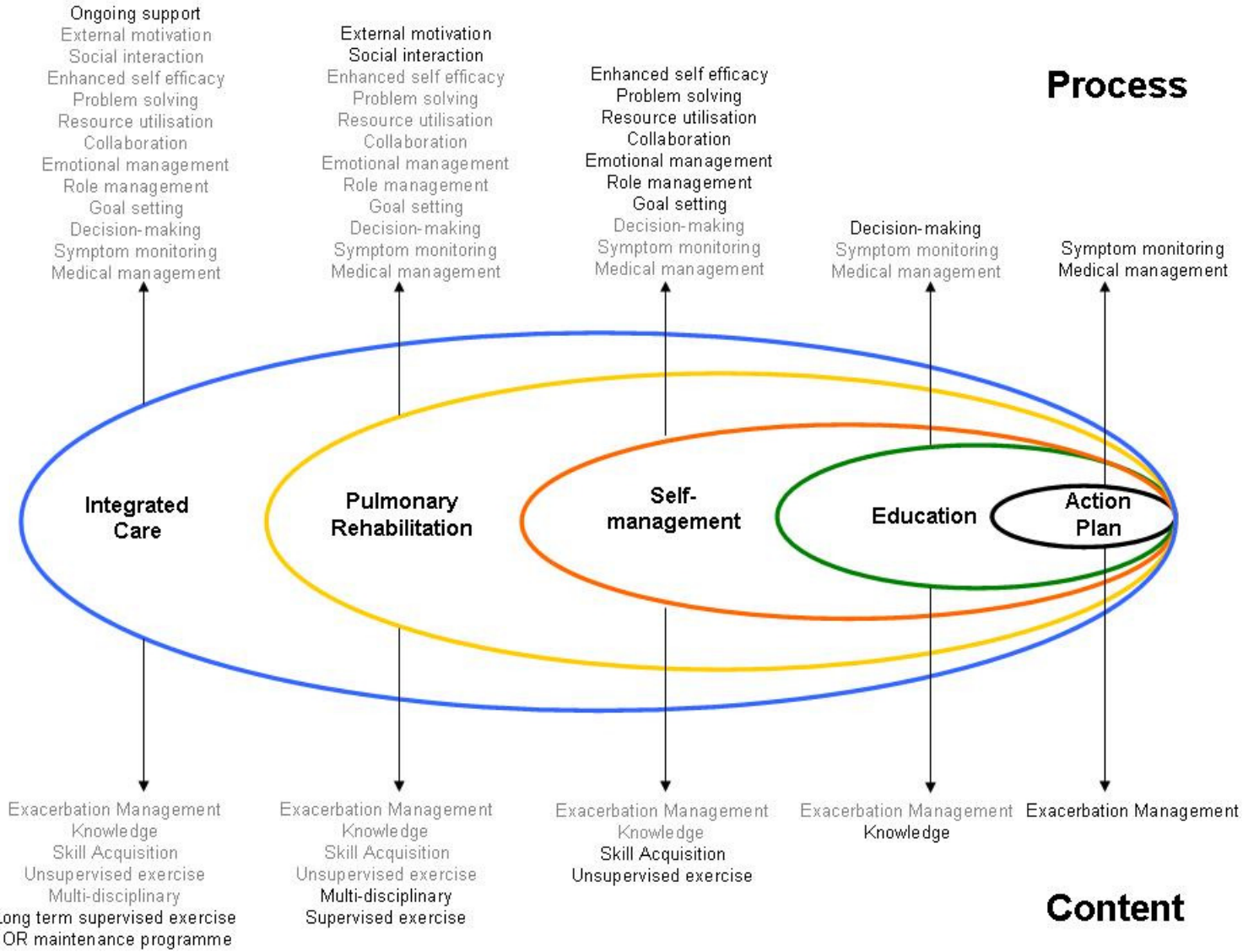


Figure 2.8 shows a layered approach to self-management. The most basic level is an ‘action plan’ through to the most advanced which is ‘integrated care.’ With the addition of each layer a new set of content and processes are involved. As previously discussed the lack of clear definition of terminology in self-management can be confusing, and using the descriptions in the model may help practitioners, researchers and those involved in the field to have a clearer understanding of the different stages.

Another function of this model is to aid in the decision-making process for practitioners in terms of management of their patients. Practitioners often need to make difficult decisions about patient care, particularly in a healthcare climate where resources are constrained and interventions must be allocated carefully. While it may be desirable for all patients to receive the most comprehensive care available, this is not always possible. This model may help guide practitioners in allocation of self-management support in a tiered process; the most basic for those with milder disease and the most comprehensive for more severely compromised. The content and processes involved at each level can be used to decide upon treatment choice based on individual patient deficits and needs.

Overall it is important that the approach taken is well suited to the model of healthcare for which it is intended. In the UK, the impetus on self-management for COPD has been outlined in the Outcomes Strategy for COPD and asthma (Department of Health 2012a). While there is evidence of improved patient outcomes, the implication of being able to achieve these

benefits at low cost is necessary in order to tackle the growing burden of COPD. Highly supervised self-management courses have been more than or equally resource intensive as most pulmonary rehabilitation courses which have been implemented successfully for many years. There is scope to develop self-management programmes in the UK which aim to provide an effective treatment regime that adopts more of a 'light-touch' approach.

2.6 Literature Summary

COPD poses a significant burden on the individual, the family and the healthcare system. There are a range of general management approaches which can be employed, and include pharmacology, smoking cessation, and pulmonary rehabilitation. These therapies tend largely to be provided in a reactive response to disease deterioration. Many of the current global healthcare systems are challenged in how to appropriately manage chronic disease, and often attempt to apply strategies designed for acute care onto the management of COPD. This is usually an ill fit, as there are many differences in the characteristics and therapeutic goals of both acute and chronic illness. The Chronic Care Model proposes that healthcare provision must be reformed in order to meet the needs of people living with long-term conditions. The CCM identifies that treatment should be evidence-based, systems should be improved, performance should be monitored, regular planned follow-up included, patients should be included in decision-making, and self-management should be supported.

It is inevitable that all people living with COPD will self-manage their condition. By providing self-management support, the aim is to provide patients with the skills and knowledge that is required to enable them to make decisions that will optimise their medical and emotional well-being. To improve self-management is to embrace behaviours which will have a positive impact on health. There are, however, many factors which might influence behaviour. In supporting self-management, skills in problem-solving, decision-making, recourse utilisation, collaborative partnerships and taking action should be promoted. For individuals with COPD, there are more disease specific skills and behaviours to be addressed, including but not limited to exercise, relaxation, smoking cessation, inhaler technique, breathing control, chest clearance and exacerbation management.

There have been several studies of self-management programmes for COPD published from around the globe. The interpretation of the term 'self-management' has led to the development of great variety between programmes. Some have been as simple as an action plan, while others have provided highly intensive supervised programmes of exercise and education over substantial durations. With the aim of bringing clarity to the literature, this variety has been interpreted as a tiered approach to self-management support (figure 2.8 and appendix 2). Using this spectrum may be useful for researchers to define where along the spectrum an intervention sits, and also for practitioners to guide therapy for their patients. It is clear from the literature, however, that as yet there is no consistent message with regards to

how, who and when self-management support should be provided for people with COPD.

As yet, there is no standardised approach to self-management for COPD in the UK, and studies of programmes to date have either developed interventions which are not feasible for a UK model of healthcare, have failed to intervene or have had methodological flaws. With a need for evidence of a feasible self-management programme for COPD in the UK, this thesis describes the work of a study conducted to evaluate the impact of a new self-management programme – a Self-management Programme of Activity, Coping and Education – SPACE FOR COPD. SPACE FOR COPD is an independently followed programme which incorporates exercise training and promotes knowledge and skill acquisition. The programme is described in more detail in chapter 3. The study used a variety of outcome measures in order to reflect the range of skills required to self-manage COPD and to allow for exploration of the data in terms of health behaviour change. It was anticipated that SPACE FOR COPD would lead to improvements in clinical outcomes, when compared with usual care. The hypothesis was the SPACE FOR COPD would confer greater gains in HRQoL at six months, compared with usual care alone.

Chapter 3 Methods

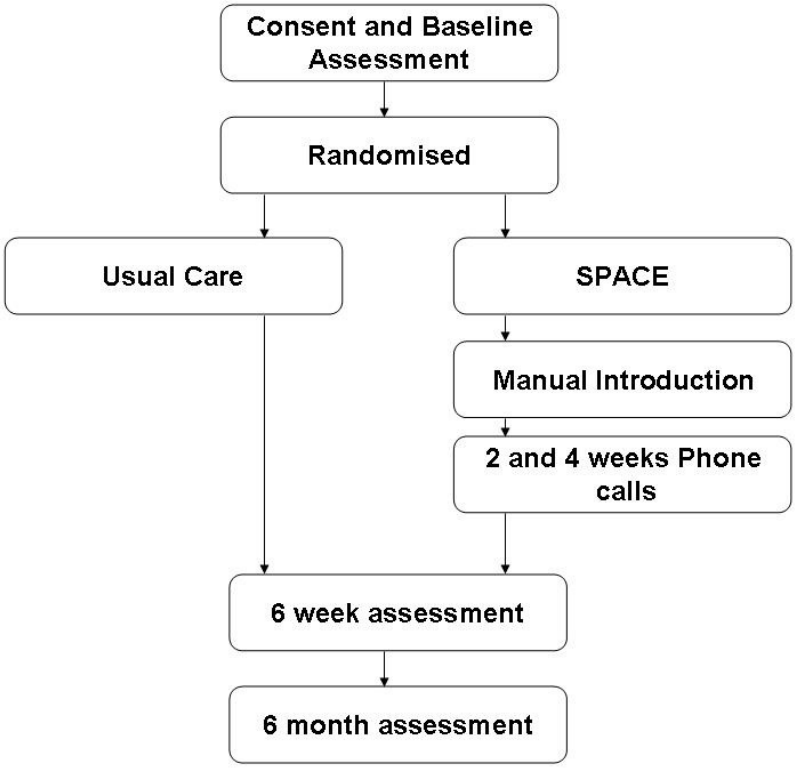
3.1 Introduction

This chapter describes the methods employed in chapters 4, 5, 6 and 7. These chapters explore the main components of the RCT described in this thesis. This includes evaluation of the effectiveness of a SPACE FOR COPD at six weeks and six months, and the impact on physical activity. This chapter will describe the study design, patient recruitment, outcome measures and provide detailed description of the SPACE FOR COPD intervention. It will also outline information on data storage and methods of statistical analyses employed in this thesis.

3.2 Main study design

This was a single blind RCT (figure 3.1). Patients were randomised to receive either usual care through their General Practitioner (GP) or to an intervention group that received SPACE FOR COPD in addition to their usual GP management. A further detailed description of the SPACE FOR COPD intervention can be found in section 3.6 and of the usual care in section 3.7 of this chapter. All participants were assessed at baseline prior to randomisation and re-assessed after six weeks of receiving their intervention and again after six months of receiving their intervention.

Figure 3.1 Study Design



3.3 Randomisation and blinding

A third party randomisation service was provided by the Leicester University Clinical Trials Unit (CTU). Simple randomisation was used and the CTU prepared a list of codes in a random order; either intervention or control. These codes were accessed by the research team via an internet-based log-in system called 'Sealed Envelope'. The research team able to access these codes were Katy Mitchell, Sally Singh and Samantha Harrison, all of whom were unblinded researchers. Upon entering the patient identification number on Sealed Envelope the researcher was provided with the next code in the

sequence. Participants randomised to 'control' received usual care and those randomised to 'intervention' received the SPACE FOR COPD intervention. Follow-up assessments at six weeks and six months were all performed by a blinded researcher (Vicki Warrington) who was unaware which group the participant had been allocated to. It was not possible to blind participants from which group they had been allocated. Participants were informed of the blinding procedure and were advised not to inform the blinded researcher of their randomisation.

3.4 Patient recruitment details

3.4.1 Ethical approval

Ethical approval for the study described in this thesis was obtained from the Leicester, Leicestershire and Rutland Research Ethics Committee Nottingham 2. Sponsorship was provided by University Hospitals of Leicester (UHL) NHS trust (appendix 3). Approval was also obtained from the Research and Development departments of Leicester City Primary Care Trust, Leicestershire County Primary Care Trust and Coventry Teaching Primary Care Trust.

Subjects were provided with a written information sheet (appendix 4) and were given at least 48 hours to consider the information and to ask any questions. Informed written consent was provided by all participants (appendix 5). It was made clear that refusal to take part or withdrawal from the study would not affect their current or future medical care.

The GPs of all participants were informed of their patients' involvement with the trial and were sent a copy of the consent form, a patient information sheet, a copy of the protocol and a covering letter. A copy of the consent form, patient information sheet, GP covering letter and a copy of their initial reply slip was filed in the UHL medical notes. If the individual did not have medical notes a new set was created. Each participant was given a copy of the consent form and a copy was kept with an information sheet in a research file. Trial registration number: ISRCTN33482179.

3.4.2 Recruitment

Participants were recruited through 30 general practices in primary care in Leicester, Leicestershire, Rutland and Coventry. Practices were approached by the Primary Care Research Network (PCRN), and those interested in assisting in recruitment were put in contact with the study team. A mail out was conducted to all patients on each practice COPD register, which provided a patient information sheet. Patients who were interested in participating in the study were asked to complete the reply slip and send to the study team to arrange screening for suitability.

3.4.3 Inclusion Criteria

Subjects were eligible to participate and to be randomised in the trial if they had airflow obstruction diagnosed with spirometry (FEV_1/ FVC ratio < 0.7) in accordance with the GOLD guidelines (Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2013), a clinical picture of COPD and self-

reported as MRC dyspnoea grade 2-5. They also had to be able to understand and read English to the level of an eight year old.

3.4.4 Exclusion Criteria

Subjects were excluded from participation if they had locomotive, neurological or cognitive impairment that would prevent engagement with the exercises provided by the SPACE FOR COPD intervention. They were also excluded if they had completed pulmonary rehabilitation within the previous 12 months.

3.5 Outcome Measures

Assessment of all outcome measures was performed at three time points: baseline prior to randomisation, six weeks from receiving the intervention and six months from receiving the intervention. The outcome measures can be divided into four main categories: exercise performance, patient reported outcome measures, healthcare utilisation and physical activity.

Baseline Visit

During the baseline visit general clerking information was collected. This included demographics, past medical history, smoking history, current respiratory-related symptoms, current medications, height, weight and social status. Resting Borg breathlessness, heart rate and oxygen saturations were recorded. Spirometry was performed in order to confirm the diagnosis of COPD. This was performed on a Vitelograph and was carried out according to the BTS guidelines (British Thoracic Society 2005). Participants that failed to show a diagnosis of COPD as previously described in section 3.3 were

withdrawn from the trial, no further data was collected and were referred back to their GP. These participants were not randomised to a study treatment group.

(1) Exercise Performance

(i) Incremental Shuttle Walking Test [ISWT (Singh et al. 1992)]

This is a standardised and externally paced field walking test that is incremental and progressive. The test has been validated for use with individuals who have COPD and it compares favourably with peak oxygen uptake as measured by conventional laboratory maximal exercise tests in this population (Singh et al. 1994). Participants were asked to walk around a 10m course along a flat hospital corridor which was marked out by two cones placed nine metres apart to allow 0.5 metres at each end for turning. The speed of walking was dictated by audio signals from a CD player. The speed began slowly and increased after each minute. The test continued until the individual was either too breathless or fatigued to continue or until the speed could no longer be maintained. The test was operated according to the standardised instructions. The total number of shuttles completed was recorded as metres. Oxygen saturations and heart rate were recorded immediately on completion of the test using a pulse-oximeter. Borg Breathlessness and perceived exertion scores were obtained upon test completion (Borg 1982).

(ii) Endurance Shuttle Walk Test [ESWT (Revill et al. 1999)]

This is an externally paced constant speed walking test of endurance capacity. This was performed following the ISWT and after allowing for a long enough rest period for oxygen saturations and heart rate to return to baseline. Participants were asked to walk around the same 10m course as described for the ISWT. The speed was again dictated by audio signals from a CD player, and after approximately 100 seconds of warm up at the slower speed, a triple bleep denoted the start of the faster endurance speed which then remained constant until the test was complete. The speed at which the individual was required to walk during the ESWT was calibrated by using their ISWT distance in the regression equation described by Singh et al. (Singh et al. 1992) to estimate their peak oxygen consumption (VO_2 peak). A speed was selected that related to the individual working at a rate of approximately 85% of their peak VO_2. The test was terminated either when the individual was too breathless or fatigued to continue or when the pace could no longer be maintained. The test was timed from the end of the warm up until completion. The maximal length of the test is 20 minutes.

(2) Patient-reported outcome measures

(i) Chronic Respiratory Questionnaire- Self Reported [CRQ-SR (Williams et al. 2001)]

This questionnaire is comprised of 20 questions which cover four domains; dyspnoea, fatigue, emotion and mastery (appendix 6). Questions are answered on a seven point Likert Scale. The dyspnoea domain is the only component which is tailored to the individual as the respondent is instructed to

self select activities which have elicited breathlessness in the past two weeks. This tool has been found to be valid in a COPD population and sensitive to change following a course of pulmonary rehabilitation (Williams et al. 2003). A change of 0.5 per domain has been defined as the minimal clinically significant difference for this group of individuals (Jaeschke et al. 1989). The questionnaire has been used extensively in people with COPD and takes about five to 10 minutes to complete.

(ii) Hospital Anxiety and Depression Scale [HADS (Zigmond and Snaith 1983)]
This is a short scale developed as a screening tool for the detection of states of anxiety and depression in a hospital or medical outpatient setting (appendix 7). It is comprised of 14 questions, seven of which give a score for an anxiety subscale and seven of which give a score for a depression subscale. The authors state that total score per subscale of eight to 10 shows a borderline state of anxiety or depression and a score greater than 10 indicates a probable state of anxiety or depression. The questionnaire takes approximately three minutes to complete.

(iii) Pulmonary Rehabilitation Adapted Index of Self-Efficacy [PRAISE (Vincent et al. 2011)]
Adapted from the General Self-Efficacy Scale, the PRAISE includes the original 10-item questions alongside an additional five items which are disease specific (appendix 8). Individuals are instructed to reflect on each statement on a four point Likert type scale as to whether it is ‘not at all true’, ‘hardly true’, ‘moderately true’ or ‘exactly true’. The score range per question

is one to four, giving a total score range of 15-60. A higher score indicates greater self-efficacy. It has been validated in a COPD population and has shown to be sensitive to change following pulmonary rehabilitation (Vincent et al. 2011). It takes around five minutes to complete.

(iv) Bristol COPD Knowledge Questionnaire [BCKQ (White et al. 2006)]
A measurement of knowledge, the BCKQ is a self-reported multiple choice questionnaire (appendix 9). It is divided into 13 topics; In COPD, COPD, symptoms, breathlessness, phlegm, chest infections/ exacerbations, exercise, smoking, vaccinations, inhaled bronchodilators, antibiotic treatment, steroid tablets for COPD and inhaled steroids. Each topic contains five statements and the respondent is instructed to indicate whether they think the statement is true, false or if they don't know. A score of one is allocated for a correct answer and zero for an incorrect answer and for all answers marked as 'don't know'. The score range is zero to 65, and a higher score indicates better knowledge. The questionnaire has been validated in a COPD population, has shown to be sensitive to change following pulmonary rehabilitation (White et al. 2006) and takes around 10 minutes to complete.

(3) Healthcare Utilisation

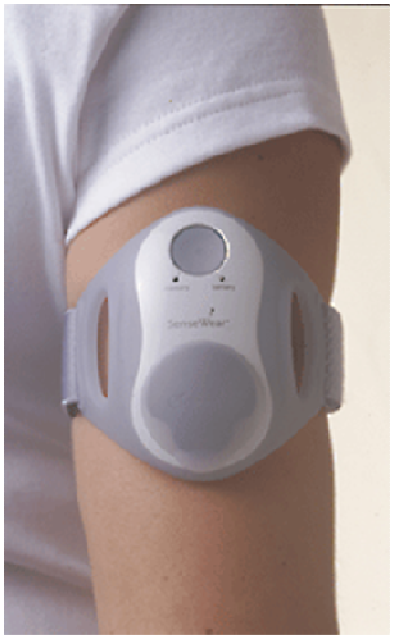
Utilisation of both primary and secondary healthcare resources was captured by retrieving data directly from electronic records held by the participants' GP practices and local hospitals. Participants were also asked to report their healthcare utilisation in order to capture data which may have been missed, such as any healthcare visits which might have occurred out of the area. Visits

to the GP, practice nurse, other healthcare professional, emergency department visits, hospital admissions were recorded for both respiratory and non-respiratory related causes. Courses of antibiotics and steroids were also recorded.

(4) Physical Activity

The SenseWear Armband (SAB) Pro3 (Bodymedia, Pittsburgh) physical activity monitor is a portable lightweight device which is worn on the upper right arm (figure 3.2) and provides a measure of 'free living' activity. It is a multi-axial accelerometer which uses specific algorithms to determine total energy expenditure, time and energy expenditure over a METs threshold and number of steps. It has been validated against a visual count of steps at various speeds in both healthy and COPD populations (Hill et al. 2010a). Reliability was found to weaken with slower walking speeds, however was still preferential to a conventional pedometer (Turner et al. 2012). Individuals were instructed to wear the SAB for seven consecutive days during all waking hours, other than when the monitor might get wet, such as taking a bath/ shower or going swimming. The monitor was worn for a seven-day period following each of the baseline, six-week and six-month assessments.

Figure 3.2 Placement of the SenseWear Armband



3.6 The SPACE FOR COPD Intervention

The SPACE FOR COPD manual is a 176 page workbook which is composed of information directed at providing individuals with COPD with knowledge and skills with which to manage their condition (figure 3.3). The main components are: drug management, symptom management, management of psychological consequences, lifestyle, social support, communication and incorporates goal setting and action plans. The manual is comprised of four stages, which aim to gradually introduce new topics to the individual over time. For a full list of contents see appendix 10.

Figure 3.3 Front cover of the SPACE FOR COPD manual

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

3.6.1 The SPACE FOR COPD manual introduction

All participants who were randomised to 'intervention' received the SPACE FOR COPD manual. It was introduced to the participants by a healthcare professional (HCP) on a one-to-one basis at the individual's home during a single 30-45 minute consultation. The purpose of this session was to introduce the individual to the contents of the manual, to identify learning needs and to employ motivational interviewing techniques to discuss the individual's willingness to change.

Introduction to the contents of the SPACE FOR COPD manual

The aerobic training component of the manual advises individuals to participate in a daily timed walk, and is described in stage one of the manual. Initially this is broken down into manageable periods of walking as dictated by

the individual's level of dyspnoea, with the overall aim of achieving 30 minutes of exercise five times per week. The HCP completed sections in the manual which notified the speed and duration of walking that was achieved by the individual during the ESWT. Participants were advised to complete their daily walk at that pace which should feel 'brisker than their normal and comfortable walking speed.' The aim of the daily walk was to increase the duration by a few seconds each day. The manual contains a walking diary in which participants were instructed to record their longest walk of the day, their total walking time of the day (in the event they did more than one walk) and to use a zero to 10 scale of how hard they found the walk (appendix 11). It was advised that each walk should be terminated when the individual scored between four and six on this scale.

Resistance training exercises are described in stage three of the manual. They were discussed during the introduction; however, individuals were informed not to commence this stage until a review had taken place two weeks later. For a description of the resistance training exercises see appendix 12. The manual provides instructions that each exercise should be carried out for three sets of eight repetitions, and should be carried out three days per week. Individuals were asked to complete a diary of resistance training, which details the weight used, the number of repetitions completed and the level of difficulty on a zero to 10 scale for each exercise.

The action plan was also explained to the patient by the HCP during the initial introduction (appendix 13). Each person receiving the manual was asked

about their frequency and current management of infections or exacerbations. Patient details, current medications and emergency medications were completed on the form. Signs and symptoms of an exacerbation were highlighted by the HCP and forms of management were identified. The individual was directed to the pages in the manual which could be useful in the management of their exacerbations.

Identification of learning needs

The results from the baseline BCKQ were observed by the HCP, and any areas of deficit were highlighted and used to prompt the patients about possible learning needs. Participants were shown the contents page of the manual and asked to discuss topics of interest or areas which they felt inclined to know more about which helped to identify any other learning needs which had not been detected from the BCKQ.

Motivational Interviewing (MI)

A key aim of the manual is to support the individual in making changes in health behaviours which have led to or may alleviate the symptoms of COPD. This is largely done through a process of providing knowledge, promoting self-efficacy and goal setting. It was also facilitated by the HCP through MI, with particular respect to commencing the exercise programme. The HCP conducting the introduction was trained in MI. The purpose of the MI discussion was to establish the individual's willingness to participate in the exercise programme by exploring issues of confidence and importance, to discuss the pros and cons to change and to identify motivating factors and

possible barriers. The duration of MI varied dependent upon the individual's response. The greater the ambivalence that was displayed the more time was spent on this discussion.

Readiness to change was evaluated and discussed by using 'readiness rulers'. Individuals were asked on a scale of one to 10 how important it was to them and how confident they were to undertake a daily walking programme. The individual's responses to these questions were used to provoke further discussion, supporting self-efficacy to enhance motivation. Various forms of reflections and rolling with resistance were used by the HCP to reinforce change dialogue from the patient. Preserving the individual's autonomy was an important aspect of the consultation, and goals which were set were made by the patient and not the HCP.

3.6.2 Telephone support

Each participant who received the SPACE FOR COPD manual received two phone calls from the HCP who had conducted the introduction. They took place two and four weeks following the 30-45 minute introduction. The purpose of the telephone calls was to monitor and review progress of the exercise programme, continue the use of MI and provide encouragement. Individuals were also given the opportunity to ask questions or discuss problems related to working through the manual. The consultation was expected to be approximately five minutes. A copy of the telephone contact schedule is provided in appendix 14.

3.7 Best usual care

All participants maintained access to their best usual care provided by their GP. For those randomised to the 'control' group, this was the only form of management that was received. Participants were recruited from 25 GP sites therefore it was not possible to standardise for all participants. Pharmacological management and an annual review comprising spirometry, MRC dyspnoea grade assessment, smoking status are common features of usual care. No participants were referred to pulmonary rehabilitation as part of their usual care during that study period.

3.8 Data storage

Notes were kept in a locked filing cabinet and were identifiable only by the participant identification number. All electronic files containing individual data were kept on a network drive of UHL in a password protected file that was only accessible by the research team. A copy of the log of study visits and a copy of the outcome summary was filed in the patients' hospital medical notes and distributed to the GP. All paperwork and electronic files will be kept for 15 years in line with UHL policy.

3.9. Sample size

This study was powered on the primary outcome of the CRQ-SR dyspnoea domain at six months. To detect a between-group difference of mean (SD) 0.5 (1.0) a sample size of 62 per group was required for 80% power, two-tailed tests (α0.05). In anticipation of up to a 30% attrition rate, the total sample size was increased to 184.

3.10 Statistical analysis

Statistical support was provided by the trial statistician at the University of Leicester (JB). Data was predominantly analysed using Predictive Analytics Software [PASW previously known at Statistical Package for Social Science (SPSS)] version 18. STATA was used to carry out multiple imputations for missing data and Statistical Analysis Software (SAS) was used in the analysis of physical activity data in chapters 6 and 7. For the main outcomes at six months, an intention to treat approach was planned. The level of significance throughout was set at $p<0.05$. Data was screened for outliers. All data was assessed for normality so that appropriate parametric or non-parametric tests could be conducted. Normally distributed data are expressed as mean and standard deviation (SD) and non-normally distributed, or categorical data are expressed as median and inter-quartile (IQR) range or frequency and percentage.

Between-group differences in baseline characteristics were compared with either independent t-tests for continuous data or chi square tests for categorical data. These tests were used again to test for differences between those who completed and those who did not complete the study.

Between-group comparisons at six weeks were made using independent t-tests and Mann-Whitney U tests for parametric and non-parametric data respectively. Within-group changes at six weeks were analysed with paired t-tests or Wilcoxon tests for parametric and non-parametric data respectively.

To correct for baseline differences between groups, analysis of covariance (ANCOVA) was performed.

At six months, an intention to treat (ITT) analysis was carried out. STATA was used to create 10 models of multiple imputations for missing data, according to a multiple imputations chained equations (MICE) technique (Azur et al. 2011). To analyse between-group differences and within-group changes at six months, repeated measures analysis of variance (ANOVA) was employed.

SAS was used to calculate bouts of baseline physical activity. A Kruskal-Wallis test was used to test for differences in activity between MRC grades and GOLD stages, and a Mann Whitney U used for post hoc analyses. Bouts of activity were compared with total activity by using a Wilcoxon signed rank test. Linear regression was conducted in order to establish whether any characteristics or baseline variables were able to predict change in physical activity. All statistical procedures relevant to each chapter (chapters 4-7) are described individually.

Chapter 4 SPACE FOR COPD – results at six weeks.

4.1 Introduction

There have been many studies published of self-management programmes for COPD, however, results of trials have been inconsistent. The literature gives no clear indication as to why some studies have had better improvements than others. Even with the publication of more self-management studies since the Cochrane Review of self-management in 2007 (Effing et al. 2007), the message that there is considerable heterogeneity between interventions, outcomes and follow-up remains.

Time to follow-up is important to consider. Many studies initiated primary follow-up contact at anything between three months to seven or 12 months in the case of one study (Effing et al. 2011). A potential problem with not performing short-term follow-up is that treatment differences in this early period will not be detected. Self-management studies which have not performed outcome measures until seven months may have missed the opportunity to detect greater between-group differences and therefore fail to identify the need for any further support. The duration of the intervention should also be considered, as it may be supposed that programmes of longer duration would yield better results. The 'intervention period' of SPACE FOR COPD was six weeks, therefore it is important to measure the short-term impact.

This chapter will describe the short-term (six weeks) phase of the RCT described in chapter 3. Patients were recruited and randomised to receive usual care, or usual care plus SPACE FOR COPD. Patients were assessed at baseline and again six weeks later.

4.2 Aims

This chapter aims to explore the following:

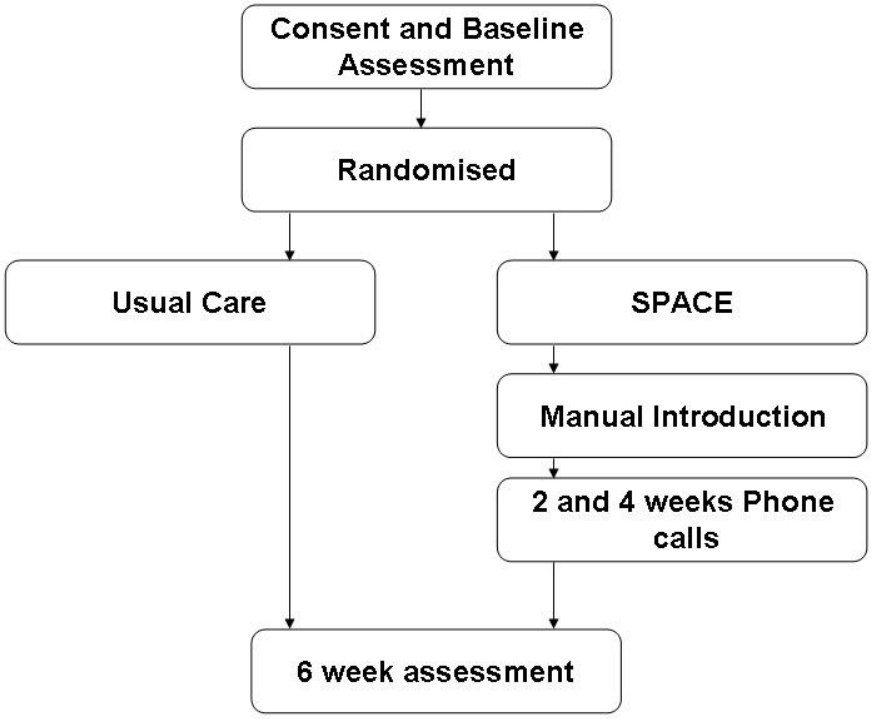
i) Between-group change in outcomes at six weeks

ii) Within-group response to treatment at six weeks

4.3 Methods

The methods for the study are described in detail in chapter 3. Please refer to this chapter for details related to recruitment, randomisation, blinding, outcome measures and a description of the intervention and usual care. The design of this aspect of the trial is outlined in figure 4.1.

Figure 4.1 Study Design at six weeks



Outcome Measures

The outcome measures used in this study are described in detail in chapter 3.

The outcome measures included were:

Chronic Respiratory Questionnaire – Self Reported (CRQ-SR) dyspnoea, fatigue, emotion and mastery domains

Hospital Anxiety and Depression Scale (HADS)

Incremental Shuttle Walking Test (ISWT)

Endurance Shuttle Walk Text (ESWT)

Bristol COPD Knowledge Questionnaire (BCKQ)

Pulmonary Rehabilitation Adapted Index of Self-Efficacy (PRAISE)

Power Calculation

This study was powered to detect a between-group difference of mean (SD) 0.5 (1.0) on the CRQ-SR dyspnoea domain at six months. For 80% power, 2-tailed tests, 62 participants per group were required. Anticipating a 30% drop out rate, the aim was to recruit 92 participants per group, a total sample size of 184.

Self-management Programme

SPACE FOR COPD is an independent, individualised and standardised workbook for people with COPD, and is described in greater detail in chapter 3. The aim of the programme is to support individuals in learning self-management and disease specific skills that will enable them to improve health behaviours, such as exercise, smoking behaviour, stress management, breathing control and exacerbation management. Individuals randomised to the intervention arm of this study were introduced to the manual by a physiotherapist (KM). During this introduction motivational interviewing was used to discuss readiness to change, and the manual contents and the home exercise programme within SPACE FOR COPD was described to the patient. The exercise programme was to be conducted entirely at home, unsupervised, and consisted of daily walking and resistance training. Goal-setting and problem solving strategies were embedded in the manual and supported by the therapist during the introduction. Patients then received two standardised phone calls from KM to assess progress, identify challenges and encourage progression. These occurred two weeks and four weeks from

initiation of the intervention, and example of the phone call pro forma is included in appendix 14.

Usual care

All participants continued to receive their usual care; however, patients randomised to the control group received no additional treatment. Usual care could not be standardised as it was embedded in clinical services, and withholding care would be considered unethical. Routine clinical care in the UK, however, usually consists of an annual review from their practice nurse which includes spirometry, and review of pharmacotherapy. No patients received any other self-management programme or pulmonary rehabilitation as part of their usual care.

Statistical analysis

Statistical analyses were completed using Predictive Analytics Software [previously known at Statistical Package for Social Science (SPSS)] version 18. Baseline between-group differences were established with an independent t-test for continuous data and with chi square test for categorical data. The between-group differences in measures were compared using independent t-tests and Mann-Whitney U tests for parametric and non-parametric data respectively. For within-group comparisons, paired t-tests or Wilcoxon tests were applied on parametric and non-parametric data respectively. Analysis of Covariance (ANCOVA) was used on measures where a significant baseline difference between the two groups had occurred.

4.4 Results

184 patients were recruited and randomised to the study; 95 to usual care and 89 to SPACE FOR COPD. 11 patients withdrew from the usual care group and 18 patients from the SPACE FOR COPD group. Reasons for withdrawal are outlined in table 4.1. The total missing data at six weeks was 29, or 15.76%. Independent t-tests showed that there were no significant baseline differences between those who did and did not complete their six-week assessment (table 4.3). Baseline demographic data are described in table 4.2. Data are expressed as mean (SD) for continuous data and absolute values for categorical data. There were no significant differences between groups in baseline characteristics.

Table 4.1 Reasons for study withdrawal

Reason for withdrawal	Usual care	SPACE
Co-morbidities	2	5
Did not attend appointment	4	3
Lost to follow up	1	4
Intervention too difficult	N/A	1
Intervention too easy	N/A	1
Social	2	0
Unable to attend appointment	2	3
Work Commitments	0	3
Total	**11**	**18**

Table 4.2 Baseline characteristics of SPACE FOR COPD and usual care groups

		Usual care n=95	SPACE n=89	p value
Age (yrs) [mean (SD)]		69.9 (10.1)	69.0 (8.1)	0.502
FEV_1 (litres) [mean(SD)]		1.45 (0.55)	1.45 (0.57)	0.973
Male: Female [n (%)]		47 (49) : 48 (51)	54 (61) : 35 (37)	0.127
BMI [mean(SD)]		27.09 (4.9)	28.05 (5.6)	0.217
Age left education [mean(SD)]		15 (1)	15 (2)	0.241
MRC [n(%)]	**2**	50 (53)	48 (54)	0.595
	3	22 (23)	24 (27)	
	4	14 15)	13 (15)	
	5	9 (9)	4 (4)	
Ethnicity [n (%)	**White British**	93 (98)	87 (98)	
	Irish	2 (2)	1 (1)	0.512
	Indian	0 (0)	1 (1)	
Lives with [n (%)]	**Alone**	21 (22)	19 (21)	
	Spouse	58 (61)	54 (61)	0.750
	Family	8 (8.5)	11 (12)	
	Other	8 (8.5)	5 (6)	

Table 4.3 Baseline characteristics of completers and non-completers at six-weeks

		Completers n=155	Non-completers n=29	p value
Age (yrs) [mean (SD)]		69.6 (9.2)	69.2 (9.3)	0.851
FEV_1 (litres) [mean(SD)]		1.46 (0.54)	1.39 (0.64)	0.550
Male: Female [n (%)]		84 (54) : 71 (46)	17 (59) :12 (41)	0.501
BMI [mean(SD)]		27.71 (5.27)	26.66 (5.16)	0.327
Age left education [mean (SD)]		15.4 (1.4)	15.5 (1.9)	0.822
MRC [n (%)]	**2**	83 (54)	15 (52)	0.781
	3	40 (26)	6 (21)	
	4	22 (14)	5 (17)	
	5	10 (6)	3 (10)	
Ethnicity [n (%)]	**White British**	151 (97)	29 (100)	0.693
	Irish	3 (2)	0 (0)	
	Indian	1 (1)	0 (0)	
Lives with [n (%)]	**Alone**	36 (23)	4 (14)	0.567
	Spouse	91 (59)	21 (72)	
	Family	16 (10)	3 (10)	
	Other	12 (8)	1 (3)	

Health-Related Quality of Life (HRQoL)

The CRQ-SR is composed of four domains; dyspnoea, fatigue, emotion and mastery. The dyspnoea domain at six months is the primary outcome of this trial. There was a significant baseline between-group difference for CRQ-SR

dyspnoea domain. An ANCOVA was performed on the dyspnoea domain in order to adjust for this. Between-group differences in the change score from baseline to six weeks for all domains of the CRQ-SR are presented in table 4.4 and figure 4.2. This shows that there were statistically significant between-group differences in the change in dyspnoea, fatigue and emotion domain but not mastery. Baseline, six weeks, and within-group change scores for all domains for usual care and SPACE FOR COPD are presented in table 4.5. There were significant within-group changes in dyspnoea, fatigue and emotion domains in the SPACE group, and a significant within-group change in the dyspnoea domain in the usual care group.

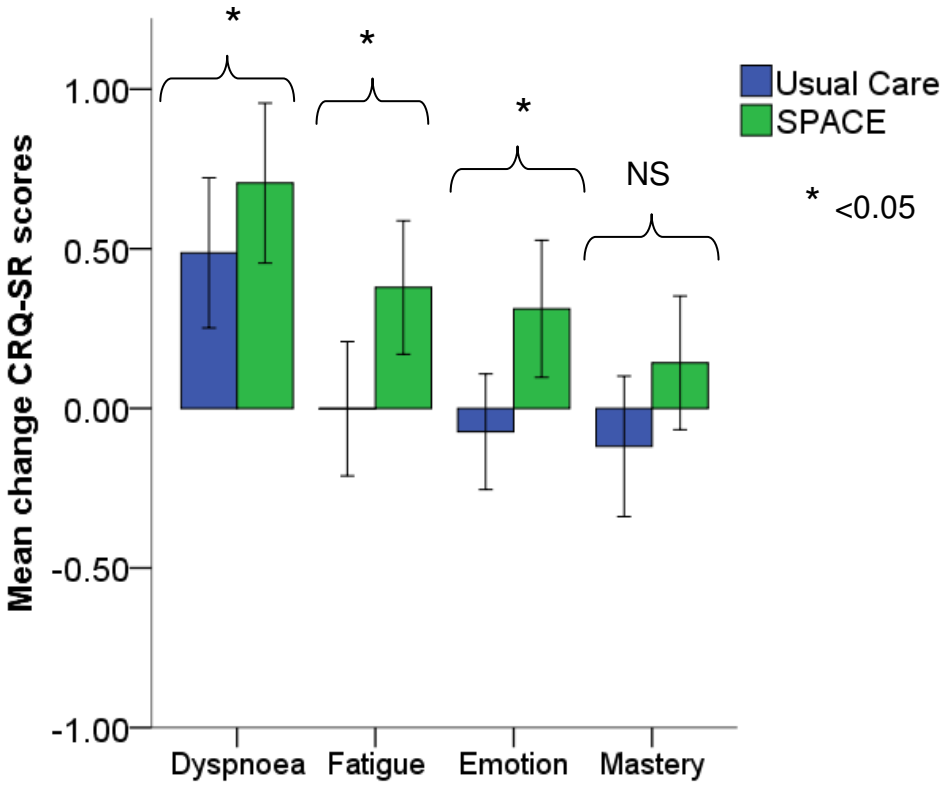
Table 4.4 Between-group differences in the change in CRQ-SR from baseline to six weeks

	Between-group difference [mean (95%CI)]	**p value**
Dyspnoea	0.33 (-0.001-0.665)	0.049
Fatigue	0.37 (0.08-0.66)	0.013
Emotion	0.35 (0.08-0.62)	0.011
Mastery	0.25 (-0.05- 0.54)	0.102

Table 4.5 CRQ-SR at baseline, six weeks and mean change for SPACE FOR COPD and usual care groups

		Mean baseline score (SD)	Mean 6 weeks Score (SD)	Mean change (95% CI)	p value
SPACE	**Dyspnoea**	3.32 (1.07)	4.02 (1.19)	0.71 (0.46 to 0.96)	<0.0001
	Fatigue	3.96 (1.20)	4.34 (1.13)	0.38 (0.17 to 0.59)	0.001
	Emotion	4.87 (1.23)	5.18 (1.17)	0.31 (0.10 to 0.53)	0.005
	Mastery	5.27 (1.30)	5.41 (1.16)	0.14 (0.07 to 0.35)	0.178
Usual care	**Dyspnoea**	2.90 (1.60)	3.39 (1.37)	0.49 (0.25 to 0.72)	<0.0001
	Fatigue	3.81 (1.28)	3.82 (1.44)	0.01 (-0.19 to 0.21)	0.939
	Emotion	4.85 (1.21)	4.80 (1.31)	-0.04 (-0.21-0.13)	0.633
	Mastery	5.20 (1.37)	5.10 (1.47)	-0.10 (-0.31 to 0.11)	0.324

Figure 4.2 Mean changes in CRQ-SR scores from baseline to six weeks



The between-group differences in HADS scores are presented in table 4.6 and within-group changes are presented in table 4.7 and in figure 4.3. This showed significant between-group and within-group changes in the SPACE group in HADS anxiety, and no changes in depression.

Table 4.6 Between-group differences in the change in HADS from baseline to six weeks

	Between-group difference [mean (95%CI)]	**p value**
HADS Anxiety	-0.74 (-1.45 to -0.02)	0.044
HADS Depression	-0.62 (-1.36 to 0.12)	0.102

Figure 4.3 Mean change in HADS scores from baseline to six weeks

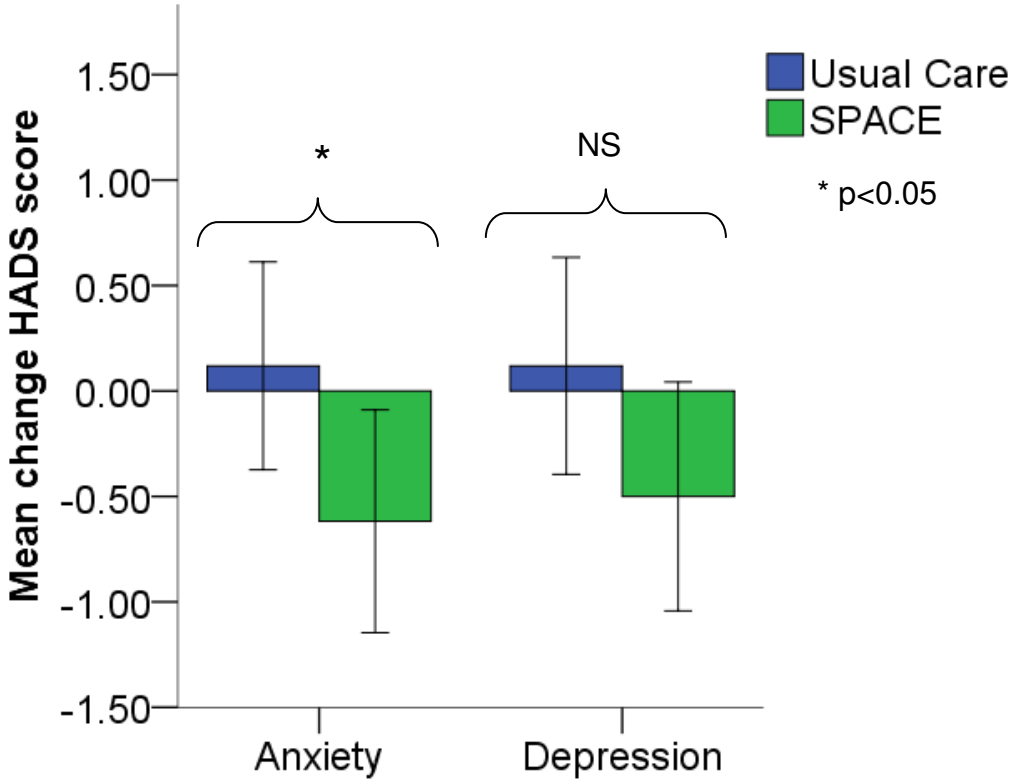


Table 4.7 HADS baseline, six weeks and mean change scores for SPACE FOR COPD and usual care groups

		Mean baseline score (SD)	Mean 6 weeks score (SD)	Mean change (95% CI)	p value
SPACE	**HADS Anxiety**	5.90 (3.91)	5.28 (3.89)	-0.62 (-1.15 to -0.09)	0.022
	HADS Depression	5.29 (3.19)	4.79 (3.40)	-0.50 (-1.04 to 0.04)	0.070
Usual care	**HADS Anxiety**	6.79 (4.02)	6.90 (4.02)	0.12 (-0.37 to 0.61)	0.630
	HADS Depression	5.14 (3.05)	5.26 (3.28)	0.12 (-0.39 to 0.63)	0.645

Given that HADS scores ≥8 suggest a possible or probably presence of anxiety or depression (Zigmond & Snaith 1983), a sub-group analysis was performed on those who had a baseline score of ≥8 in the anxiety domain (n=59) and ≥8 in the depression domain (n=38). There was no significant differences between groups for change in anxiety (p=0.382) or depression (p=0.913).

Exercise Capacity.

Between-group differences in ISWT and ESWT are presented in table 4.8 and figures 4.4 and 4.5, which show that there were statistically significant between-group differences in change in ISWT and ESWT. Within-group changes are presented in table 4.9. The within-group change in ESWT was significant, while the ISWT within-group change was not significant, for both groups.

Table 4.8 Between-group differences in the change in ISWT and ESWT from baseline to six weeks

	Between-group difference [mean (95%CI)]	**p value**
ISWT (metres)	20.5 (3.8 to 37.2)	0.017
ESWT (seconds)	134.0 (39.7 to 228.3)	0.006

Table 4.9 ISWT and ESWT at baseline, six weeks and mean change for SPACE FOR COPD and usual care groups

		Mean baseline score (SD)	Mean 6 weeks score (SD)	Mean change (95% CI)	p value
SPACE	**ISWT (metres)**	334.6 (144.6)	347.4 (157.3)	12.8 (-0.9 to 26.4)	0.067
	ESWT (seconds)	262.9 (170.8)	482.5 (390.1)	219.6 (140.9 to 298.3)	<0.001
Usual care	**ISWT (metres)**	340.7 (163.8)	333.0 (164.3)	-7.7 (-18.08 to 2.7)	0.143
	ESWT (seconds)	269.5 (192.0)	355.1 (310.4)	85.6 (32.4 to 138.8)	0.002

Figure 4.4 Baseline and six weeks scores for ISWT

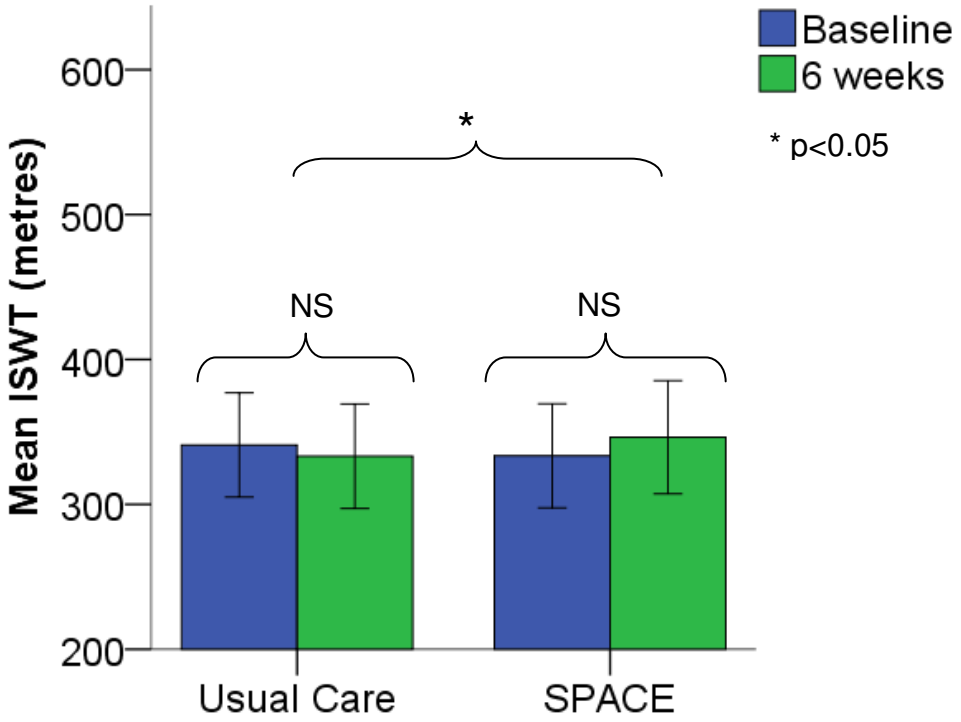
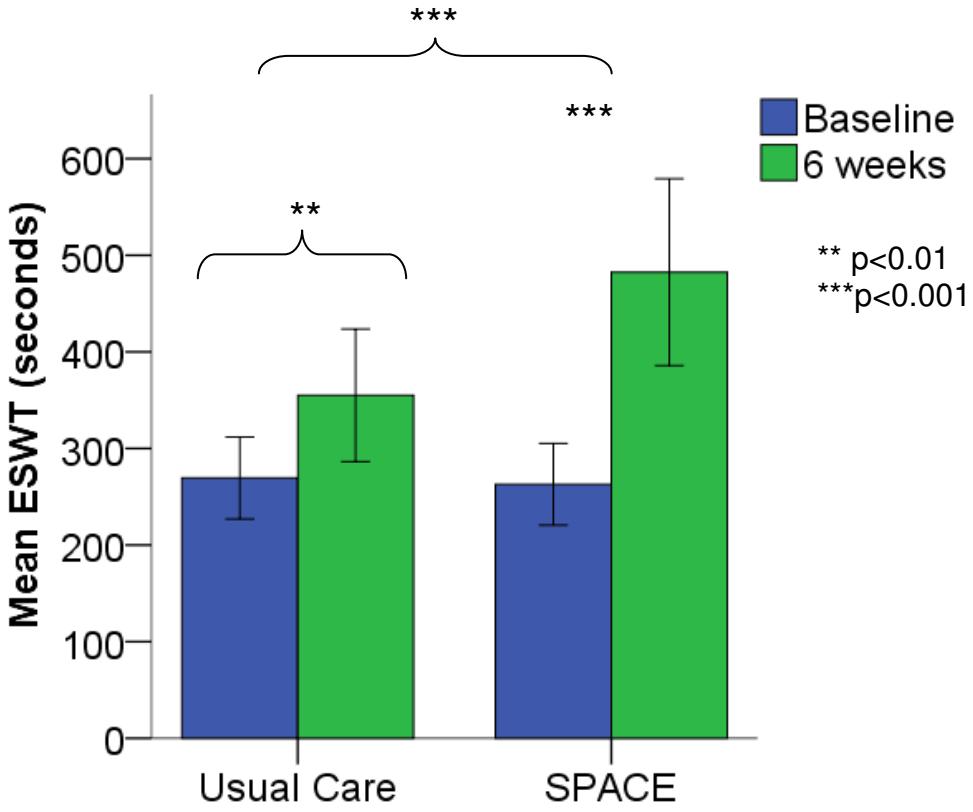


Figure 4.5 Baseline and six weeks scores for ESWT



Knowledge and Self-efficacy

Between-group differences for the BCKQ scores and PRAISE scores are presented in table 4.10. Within-group changes are presented in table 4.11. There were significant between-group and within-group changes for the SPACE group in the change in BCKQ, and no change in the PRAISE.

Table 4.10 Between-group differences in the change in knowledge and self-efficacy from baseline to six weeks

	Between-group difference [mean (95%CI)]	**p value**
BCKQ	2.21 (0.09 to 4.33)	0.041
PRAISE	1.54 (-0.32 to 3.39)	0.103

Table 4.11 Knowledge and self-efficacy at baseline, six weeks and mean change for SPACE FOR COPD and usual care groups

		Mean baseline score (SD)	Mean 6 weeks score (SD)	Mean change (95% CI)	p value
SPACE	**BCKQ**	34.85 (7.67)	37.38 (7.87)	2.53 (0.85 to 4.20)	0.004
	PRAISE	45.90 (6.87)	46.50 (7.61)	0.60 (-0.59 to 1.79)	0.321
Usual care	**BCKQ**	32.70 (9.80)	33.02 (10.13)	0.32 (-1.05 to 1.69)	0.644
	PRAISE	45.42 (7.91)	44.48 (7.60)	-0.94 (-2.38 to 0.50)	0.198

4.5 Discussion

The data described in this chapter refers to the six-week outcomes of an RCT which aimed to test the effectiveness of SPACE FOR COPD. Measures of health related quality of life, exercise capacity, knowledge and self-efficacy are examined in order to establish the short-term impact of SPACE FOR COPD. The findings of this chapter will be discussed under the following headings; health-related quality of life, anxiety and depression, exercise performance, knowledge, self-efficacy, limitations and conclusions.

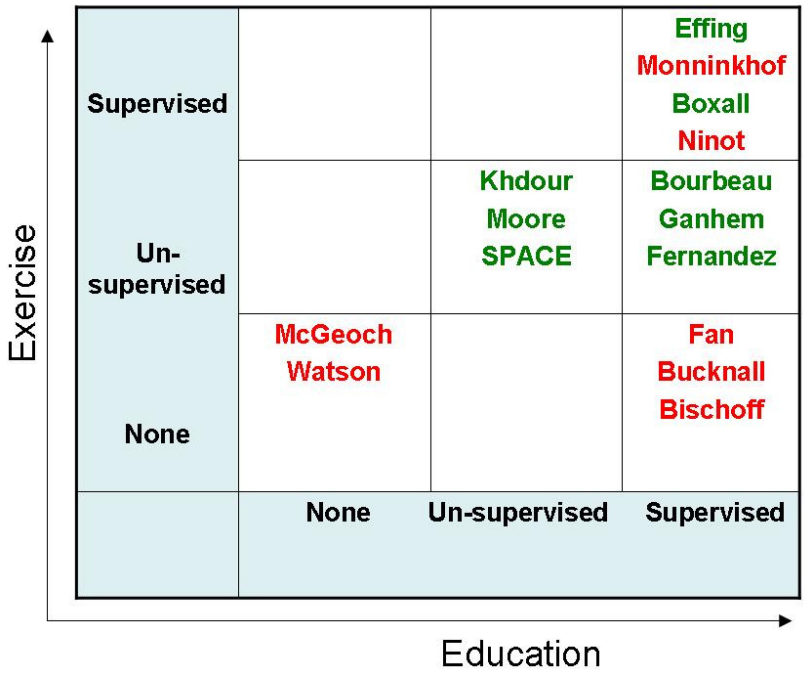
Health Related Quality of Life (HRQoL)

The results from this chapter demonstrate a statistically significant mean (95% CI) difference between the groups of 0.33 [-0.001 to 0.665 (p=0.049)] in the change in CRQ-SR dyspnoea domain. There were significant within-group

changes for both SPACE FOR COPD and usual care groups, however, only the SPACE FOR COPD group exceeded a mean change of ≥ 0.5, which is the MCID (Jaeschke, Singer, & Guyatt 1989). Statistically significant between-group and within-group changes were also observed in the fatigue and emotion domains of the CRQ-SR. No changes were observed in the mastery domain. These findings suggest that SPACE FOR COPD confers greater benefits in HRQoL, compared with usual care, at six weeks. As previously discussed in chapter 2, other self-management programmes for COPD have had mixed success in their impact on HRQoL. It is worthwhile to consider how the findings from SPACE FOR COPD compare with the literature so far.

Figure 4.6 has been adapted from figure 2.6 in chapter 2, with the SPACE FOR COPD study incorporated. SPACE FOR COPD is allied with the studies by Khdour et al. (2009) and Moore et al. (2009), insofar that it is based on unsupervised education and unsupervised exercise training. All three of these programmes have demonstrated a positive impact on HRQoL, suggesting that a 'light-touch' approach to self-management can be effective in promoting patient benefit. This is likely to be an important consideration for policy makers, who will want to provide effective programmes with as limited resources as possible.

Figure 4.6 Grid of outcomes on HRQoL (including SPACE FOR COPD)



RED = no impact on HRQoL

GREEN = significant impact on HRQoL

While the study by Moore et al. (2009), with only 27 participants, was likely to be underpowered, the study by Khdour et al. (2009) was a large RCT. Interestingly this was also a manual-based programme, delivered during a one-hour consultation, supported by motivational interviewing (MI) and reinforcement through telephone contact. Although only the Khdour et al. study and the SPACE FOR COPD study have used this kind of approach, both have had a successful impact on HRQoL. MI has previously been identified as a useful technique for influencing behaviour change (Hettema et al. 2005). In an expert review (Effing et al. 2012) it was suggested that cognitive components such as cognitive behavioural therapy (CBT) or MI

should be considered as part of future self-management interventions. This may be important for changes in HRQoL. The success of these two studies suggests that for programmes adopting a light-touch approach, motivational interviewing may be a useful technique.

Other self-management studies which have been successful in improving HRQoL, with the exception of COPE II, have mostly included more severe patients (Bourbeau et al. 2003; Boxall et al. 2005; Ghanem et al. 2010), whereas several unsuccessful studies have recruited milder patients (Bischoff et al. 2012; McGeoch et al. 2006). This may be as a result of a ceiling effect in those who are milder, whereby high baseline scores leaves little room for improvement. Patients who are more severe at baseline have more to gain, and therefore studies which have recruited more severe patients may have appeared to be more effective. However, both the SPACE FOR COPD study and COPE II (Effing et al. 2011) have recruited milder patients and have demonstrated significant improvements in HRQoL. A comparison of these studies requires further attention.

Although the COPE II study population was slightly younger (mean age ~ 63 yrs), their degree of airflow obstruction was similar to that of the patients in this study [1.43 litres (COPE II self-management) and 1.40 litres (COPE II usual care) vs. 1.4 litres SPACE FOR COPD intervention/usual care]. The COPE II intervention included six months of compulsory supervised exercise three times per week and an optional additional five months supervised

exercise twice weekly. In addition to this all patients had two hour small-group education sessions for four weeks and telephone support. COPE II was powered for ISWT and 142 patients were followed up. At the end of the intervention period (12 months) a mean (95% CI) between-group difference of 0.32 [-0.03 to 0.67 (p=0.04)] for the dyspnoea domain of the CRQ-SR was observed. This is a remarkably similar between-group difference achieved in the present study after just six weeks. For the other domains, mean (95%CI) differences for the COPE II group were 0.09 (-0.34 to 0.52), 0.10 (-0.22 to 0.42) and 0.11 (-0.21 to 0.43) for fatigue, emotion and mastery respectively, none of which were statistically significant. This is contrast to SPACE FOR COPD where significant differences in both fatigue and emotion domains were observed.

One similarity between the two studies is that the baseline values of the CRQ-SR domains are all relatively high (mean baseline scores between 4.13-5.35 for COPE II and 3.81-5.27 for SPACE FOR COPD) compared with other studies (Evans et al. 2010;Sewell et al. 2006). This may afford less opportunity for improvement. This may be particularly true for the mastery domain, which in the current study was the highest of all domains at baseline (5.27 for SPACE FOR COPD and 5.20 for usual care). It is possible that in this group of patients that there was little deficit in mastery on commencing the study, therefore the intervention would be unlikely to make a difference, as might have been anticipated prior to recruitment.

These studies both suggest that significant gains in HRQoL can be achieved in milder patients with higher baseline scores. It is interesting, however, that despite the intensity of the COPE II programme, and a similar population, gains in HRQoL were greater in the SPACE FOR COPD group after just six weeks than were achieved after either seven or 12 months on COPE II. As COPE II did not take measurements any sooner than seven months, it is not possible to understand whether between-group differences may have been greater earlier within the intervention period, and then began to decline by seven months. However, as a model of self-management support, it would be difficult to justify the costs of an intervention which requires the infrastructure of COPE II, given that the light-touch approach of SPACE FOR COPD appears to be just as, if not more, successful in improving HRQoL.

Timing of outcome measures is important, and this is the first self-management programme in stable outpatients to demonstrate significant changes in HRQoL are initiated over such a short period. Moore et al.(2009) demonstrated significant improvements at eight weeks, however as previously stated, this is likely to be underpowered. Ghanem et al.(2010) found significant improvements after two months, however this was in a post exacerbation population where the opportunity to recover may be greater. All other studies have documented changes between three and 12 months.

Outcome measures were conducted at six weeks in the present study as this was considered to be the amount of time required for significant changes in health outcomes to occur. Other studies which have a longer intervention

period have conducted outcome measures at the end of their intervention periods. The findings from the present study are important because it demonstrates that significant changes in HRQoL can occur over a short duration, and suggests that perhaps self-management interventions do not necessarily need to be as long in duration as some other studies have provided. This information is useful for healthcare professionals who provide self-management support to patients, so that they can plan early follow-up and establish progress at an earlier stage. Furthermore, in financially constrained services, programmes of shorter duration are likely to be favourable. However, the medium- and longer-term maintenance of these outcomes must be considered. This will be evaluated in chapter 5.

Anxiety and depression

The HADS is a frequently employed measure of anxiety and depression, and as has been used across a spectrum of diseases. Pre-defined thresholds of zero to seven is normal, eight to 10 indicates possible presence anxiety/depression and ≥11 a probable presence of anxiety/depression (Zigmond & Snaith 1983). The MCID has been estimated at around 1.5 (Puhan et al. 2008).

The mean baseline scores in both groups for anxiety and depression were within the normal range. There was a statistically significant between-group difference in change in anxiety scores from baseline to six weeks of mean (95%CI) -0.74 (-1.45 to -0.02) p=0.044 (lower scores= improvement). A sub-group of those who scored ≥8 at baseline (n=59) revealed no significant

between-group changes from baseline to six weeks (p=0.382). It has been documented that anxiety contributes significantly towards functional impairment for patients with COPD (Kim et al. 2000) and is associated with increased risk of exacerbations (Eisner et al. 2010). It is therefore considered an important health outcome.

Despite the prevalence of anxiety (Harrison et al. 2012), only three self-management programmes have evaluated the impact of self-management on anxiety. The COPE II study (Effing et al. 2011) used the HADS and found no difference between groups in anxiety at 12 months with a mean (95% CI) difference of 0.05 (-1.00 to 0.90). Similarly to the current population, baseline anxiety scores were also within normal range. In contrast to the intensive COPE II programme, the study by McGeoch et al. (2006) investigated the impact of an action plan for exacerbation management. The impact on HADS anxiety was a mean (SD) change of 0.15 (0.7) in the intervention group and 0.01 (0.3) in the control (p=0.87 between groups). Most recently the Glasgow Supported Self-management Trial demonstrated a significant reduction in anxiety [treatment effect -1.06 (95%CI -2.08 to -0.03), p=0.44] at 12 months (Bucknall et al. 2012). These participants were quite a different group to the present study, recruited following hospital admission and more severe, with higher baseline scores [mean (SD) 9.7 (4.6)]. The poor response rate of the questionnaires (61%) in the Glasgow study might reflect a selection bias, whereas those whose anxiety did not improve did not complete the assessment.

It seems counterintuitive that for those who scored more than 8 on the HADS that anxiety or depression did not significantly improve. The SPACE FOR COPD manual includes several sections which are designed to deal with emotions and anxiety management, therefore it might be anticipated that, for those who are anxious, the availability of these techniques should reduce anxiety levels. There are several points to consider as to why, for those with high baseline scores, anxiety did not significantly improve.

The unsupervised aspect of the SPACE FOR COPD programme, may not lend itself to improving anxiety for those who are most anxious. Bouts of exercise have been documented as precipitating panic attacks (Maurer et al. 2008) and it has been shown that dyspnoea is strongly associated with anxiety (Cleland et al. 2007; Eisner et al. 2010; de Voogd et al. 2011). It is possible that the unsupervised exercise programme that patients are advised to do at home may stimulate feelings of anxiety in response to an increase in dyspnoea on exercise. Supervised exercise training, like pulmonary rehabilitation, has shown to reduce anxiety for those who score highly at baseline (Harrison et al. 2012). Monninkhof et al. (2004a) conducted a qualitative analysis on patients who attended their supervised self-management programme. A key finding was that many patients felt safer from participating in the study, and found the presence and constant re-assessment from the healthcare professional reassuring. The safety net of supervision from a healthcare professional may be important for those who have symptoms of anxiety in order to reduce fears and concerns around safety and the presence of dyspnoea. It is possible that for those with high

baseline anxiety scores, SPACE FOR COPD is too 'light-touch' and that these patients may require more supervised care from a healthcare professional in order to reduce anxiety.

Furthermore, while we might anticipate that increased knowledge will reduce anxiety, this may not necessarily be the case. One study of people with COPD demonstrated that the patients who were highly anxious had better knowledge scores (Dowson et al. 2004). The authors suggest this is perhaps because people who panic are more motivated to seek information. However, they were more likely to catastrophise any threats to health (such as dyspnoea) which would inhibit appropriate behaviour. This study suggests that for those who are more highly anxious, education may be insufficient, and perhaps more comprehensive interventions are required. While SPACE FOR COPD is more than an education programme, and incorporates paper exercises for assisting patients to identify coping strategies, we have no measure of how well these aspects of the manual were used. Furthermore, these exercises may not be comprehensive enough for those who are most at risk of symptoms of anxiety.

We should also consider whether the HADS is the most appropriate measure of anxiety in this population. The HADS measures general anxiety and depression, however, in people with COPD much of the anxiety people experience may be more disease-related. The HADS, therefore, may not be the most sensitive tool for detecting changes in disease-specific anxiety in this group.

Finally, we must remain aware of the small numbers of people who scored 8 or higher at baseline (n=59). It is likely that this sub-analysis is underpowered for detecting any significant change.

The mean (95% CI) between-group difference in change in depression from baseline to six weeks was -0.62 (-1.36 to 0.12) p=0.102. Depression has only been reported by the same three self-management studies which examined anxiety. COPE II observed a mean (95%CI) between-group difference of -0.41 (-1.31 to 0.49), which was not statistically significant (Effing et al. 2011). McGeoch et al. (2006) found a mean (SD) change of 0.29 (0.29) in the self-management group and 0.04 (0.32) in the usual care group (p=0.57 between-group difference). There was also no significant change in depression in the study by Bucknall et al. [treatment effect (95% CI) -0.27 (-1.13 to 0.59) p=0.538 (Bucknall et al. 2012)]. It is possible that, for those who are depressed, self-management support is too subtle an intervention to reduce depressive symptoms, particularly as self-management requires a degree of patient motivation. Perhaps depression should be targeted by more intensive treatments first, such as cognitive behavioural therapy (CBT).

Exercise Performance

Exercise performance was measured by the ISWT and ESWT. There was a statistically significant between-group difference in the change from baseline to six weeks for the ISWT of mean (95%CI) 20 (3.78 to 37.18) metres p=0.017, and for the ESWT of 133.99 (39.66 to 228.32) seconds (p=0.006).

This suggests that SPACE FOR COPD was more effective than usual care in improving exercise performance.

Effing and colleagues found changes in ISWT of a similar magnitude as the present study; however this was after a 12 month period of supervised training (Effing et al. 2011). Other self-management studies have documented improvements in exercise performance, but no other adequately powered studies have performed outcome measures as early as six weeks. It is an important finding from SPACE FOR COPD that changes in exercise behaviour can be observed over such a short time frame. Understanding the course of self-management and when behaviour change occurs is important, so that expectations of our patients can be managed, and that outcome measures can be performed at appropriate time points in order to evaluate individual progression. Early evaluation also allows us to test whether the intervention works, and then to evaluate maintenance strategies to follow.

An interesting feature of SPACE FOR COPD, which is not common to all self-management programmes, is that the exercise was entirely unsupervised. Indeed, some self-management programmes include no exercise at all (Khdour et al. 2009; McGeoch et al. 2006; Watson et al. 1997) and have had rather limited success. While guidelines for pulmonary rehabilitation state that at least some exercise should be supervised (Nici et al. 2006), there are no such guidelines for self-management. There may be several possible benefits of supervised training, however, findings in this chapter suggest that entirely

unsupervised training is superior to usual care, and is able to yield a significant changes result over a six-week period.

Given that training was unsupervised the magnitude of change in the ISWT and ESWT might not be as great as expected from a supervised regime over such a period. For endurance training, patients in the SPACE FOR COPD group were instructed to walk daily at a speed which was 85% of the maximal speed achieved on the ISWT performed on their baseline assessment. This speed was demonstrated when the manual was delivered, but otherwise patients received little indication through the training period as to whether they achieved the correct speed. It is possible that patients either underestimated or overestimated their walking speed, and therefore did not train at an optimal intensity. It is also possible that as patients trained and became fitter, some patients may have re-calibrated their speed, and started to walk more quickly as they felt they were able to. These patients may not have seen their walking times improve, and may have resulted in negative feelings towards training if the benefits were not apparent to the individual. The telephone contact at two and four weeks were designed to include this in the discussion.

Knowledge

This study showed a significant between- group difference in mean (95% CI) BCKQ scores 2.21 (-0.09 to 4.33) p=0.041. Curiously no other self-management studies have used the BCKQ, although some have used other tools to assess knowledge, all of which have found significant improvements.

Knowledge is consistently identified as a key feature in the process of behaviour change (Bourbeau et al. 2003), and is widely accepted as fundamental to self-management. It is not possible from the data presented here to determine to what extent knowledge contributes to behaviour change, however this is discussed in chapter 7.

The BCKQ has been used to assess change in knowledge following pulmonary rehabilitation (White et al. 2006), with between-group differences of around nine points, which is much higher than those observed in this study. With respect to this difference, there are two key points to consider. Firstly, the questions within the BCKQ may not be relevant knowledge for each patient, such as questions about SPACE FOR COPD, steroids or inhaled steroids. Patients who received SPACE FOR COPD were advised to prioritise reading information that was relevant for them. If an individual did not use a SPACE FOR COPD, or steroids or inhaled steroids, then this information was not relevant for them and it would not be expected that their knowledge on irrelevant questions would change. The second point is that the educational material of the manual was not tailored to the questionnaire, and therefore some of the questions within the BCKQ may not have been directly answered within the pages of the manual. In future studies it may be more useful to develop a new knowledge tool which is more relevant to the SPACE FOR COPD intervention.

Self-efficacy

There were no significant between-group differences observed in PRAISE scores at six weeks. Self-efficacy has been described as an important factor for behaviour change to occur (Bourbeau, Nault, and Dang-Tan 2004), therefore it would seem integral to enhance self-efficacy in any self-management programme. Why a change was not observed in these data is worthy of further consideration.

As discussed earlier in chapter 2, self-efficacy is specific to any given situation or task (Bandura 1977a). It is possible, therefore, for an individual to have high self-efficacy for one task and low self-efficacy for another. In order to have high self-efficacy, an individual must believe that the task is important to carry out and that carrying out the task will lead to desirable outcomes. SPACE FOR COPD aimed to address this in a number of ways, including education, problem-solving activities, barrier identification and case studies. A difficulty with measuring self-efficacy is that it is likely to vary according to the task. Self-management is multi-faceted, and SPACE FOR COPD provided support for patients to improve their management by a number of strategies, therefore measuring self-efficacy of anything specific is challenging. The PRAISE was selected to measure self-efficacy in this study (Vincent et al. 2011). The PRAISE was developed for those attending pulmonary rehabilitation, which is another form of supporting self-management. It was anticipated that the PRAISE would be the most specific measure of self-efficacy that could be aligned to the task of self-management. It is possible, however, that this was still not specific enough to measure the variety of self-

management support offered through SPACE FOR COPD. Upon reflection, the COPD Self-efficacy scale may have been a more appropriate measure (Wigal, Creer and Kotses 1991).

One of the important findings in this chapter is how soon within the course of a self-management programme clinical improvements can be observed. Several self-management programmes have provided courses of longer duration, and have therefore not reported outcome measures until between three and seven months (Bischoff et al. 2012; Bucknall et al. 2012; Effing et al. 2011; Monninkhof et al. 2003; Ninot et al. 2010). Several of these studies have reported no or limited clinical benefit (Bischoff et al. 2012; Bucknall et al. 2012; Monninkhof et al. 2003; Ninot et al. 2010). It is not possible to tell from these studies whether there were significant gains made in the short-term which were reduced by the time of follow-up, or whether the intervention just failed to intervene in the first place. What the present study offers, is the insight that important gains are made within the first few weeks of undertaking the SPACE FOR COPD course. It is, however, important now to understand how these changes are maintained in the medium- to longer-term. This will be discussed in chapter 5.

Limitations

The significant difference between the groups at baseline in the CRQ-SR dyspnoea domain was a limitation of this study, which could not have been foreseen. It is likely that this was a random occurrence, and on the whole the

two groups were well matched. It was possible to manage this limitation statistically by performing an ANCOVA. By using the baseline CRQ-SR dyspnoea score as a covariate, this test statistically adjusted for this difference and minimised the risk of bias this may have had on the findings.

Interestingly both SPACE FOR COPD and usual care groups demonstrated statistically significant within-group improvements in the CRQ-SR dyspnoea score and ESWT. However, only the intervention group breached the threshold for the MCID in the CRQ0SR dyspnoea domain. Furthermore, in both measures there was also a significant between-group difference, suggesting that SPACE FOR COPD was superior to usual care. The statistically significant within-group change in the usual care group, however, was an interesting finding and one that deserves further exploration. The impact of attention, participation bias, or the conduct of exercise testing may all have potentially interfered with the data reported in this trial. These issues will be discussed further in chapter 8 of this thesis.

The risk of type I error, whereby the null hypothesis is rejected although it is actually true, is increased by conducting a large number of comparisons. In this chapter many comparisons have been made therefore this risk may be increased. However, it should be made clear that the primary outcome of this study is the CRQ-SR dyspnoea domain at six months. It is upon this outcome, which is described and discussed in chapter 6, that the hypothesis of the study will be accepted or rejected. All other outcomes and comparisons are for exploratory purposes, and therefore the statistical significance of these

outcomes alone should be treated cautiously. It should be considered, however, that with the exception of self-efficacy, depression and mastery, all other outcomes have been significantly different between groups, suggesting that overall there is a beneficial effect of SPACE FOR COPD at six weeks.

Finally, it has not been possible from this study design to establish how well, if at all, any of the patients engaged with the self-management programme. The results which have been found indicate that the programme has been used to some extent or else it would be unlikely so many differences between the groups would have occurred. Information regarding use of the manual, however, would be able to inform us whether there was a dose-response, or which aspects of the manual were most or least useful. Unfortunately the nature of the intervention does not allow for this information to be captured. In the future a web-based version of the SPACE FOR COPD manual will allow a detailed interrogation of which aspects of the programme are used most.

Conclusions

SPACE FOR COPD confers significant improvements HRQoL, anxiety, exercise performance and knowledge at six weeks, compared with usual acre alone. This is the first self-management RCT, which is adequately powered, that demonstrates significant changes over such a short duration. Understanding that these changes can occur over a short period is important so that expectations of what can be achieved on a course of self-management can be appreciated.

These findings have demonstrated that SPACE FOR COPD is effective in improving a range of clinical outcomes, including HRQoL, exercise performance, anxiety and knowledge. The impact on depression and self-efficacy may be more limited. For those with more complex emotional needs, exploration of how better to support them on SPACE FOR COPD or other interventions which may be required is warranted.

This is one of few self-management studies to document that a light-touch approach can have such an impact on important clinical outcomes. SPACE FOR COPD has shown improvements in outcomes which are equal to, or more than, those of studies with samples of similar patients. Other studies, however, have adopted more highly supervised approaches. The effectiveness of this light-touch approach will be attractive for policy makers and healthcare providers, who want to provide self-management support for their patients, yet are constrained by financial and organisational limitations. It is now important to consider how well these effects are maintained in the medium-term.

Chapter 5 The effectiveness of SPACE FOR COPD at six months

5.1 Introduction.

The short-term analysis (six weeks) of the effectiveness of SPACE FOR COPD in primary care has been discussed in chapter 4. These findings suggest that SPACE FOR COPD conferred significant improvements in health HRQoL, anxiety, exercise performance and disease knowledge within a six-week period when compared with usual care alone. It is not yet known whether these benefits are maintained beyond this six-week period.

The maintenance of these health outcomes is of considerable interest. Several self-management programmes have failed to assess outcomes once the intervention period is complete, which offers no insight into the maintenance of outcomes once the formal support is removed. Of studies which have conducted a follow-up assessment once formal support has been completed there is a trend for results to diminish, although not back to baseline (Bourbeau et al. 2003; Khdour et al. 2009; Maltais et al. 2008). It is important to establish how well and how long outcomes are maintained in order to establish whether and when any more formal support is required.

This chapter examines outcomes in HRQoL, anxiety and depression, exercise performance, knowledge and self-efficacy at six months. This will provide an insight into the effectiveness of SPACE FOR COPD over a medium-term

period, and how well the gains made at six weeks were maintained without any on-going support.

5.2 Hypothesis and Aim

Hypothesis

SPACE FOR COPD will confer a greater improvement in dyspnoea than usual care, at six months.

Aim

To test the effectiveness of SPACE FOR COPD compared with usual care, in primary care patients with COPD after six months.

5.3 Methods

This chapter describes the follow up period of a larger trial. For an overview of the study methods please refer to chapter 3 of this thesis. This section will describe the details of the methods for the follow-up period.

Follow-up

All participants who had not withdrawn from the study were invited to the hospital for an assessment six months after the baseline assessment had been completed. At this assessment blinded outcome measures were taken. Since the blinded outcome measures were taken at six weeks, no participants had had contact with any member of the research team, other than to arrange the appointment for assessment. Patients in the intervention arm had been able to keep the manual, and at the four week phone call had been advised to

continue working through the programme indefinitely. No other support for the intervention had been offered since the four week phone call. Patients in the usual care group were given no specified advice by the research team.

Outcome measures

Primary outcome measure:

CRQ-SR dyspnoea domain

Secondary outcome measures:

CRQ-SR fatigue, emotion and mastery domains

Hospital Anxiety and Depression Scale (HADS)

Incremental Shuttle Walking Test (ISWT)

Endurance Shuttle Walk Text (ESWT)

Bristol COPD Knowledge Questionnaire (BCKQ)

Pulmonary Rehabilitation Adapted Index of Self-efficacy (PRAISE)

Healthcare utilisation

Randomisation

All participants had been randomised to either usual care or intervention, the details of which are described in chapter 3.

Sample Size

The sample required to detect a between-group difference on the dyspnoea domain of the CRQ-SR is 62 per group. A 30% drop out rate had been anticipated therefore a total sample size of 184 was recruited to the study.

Statistical Analysis

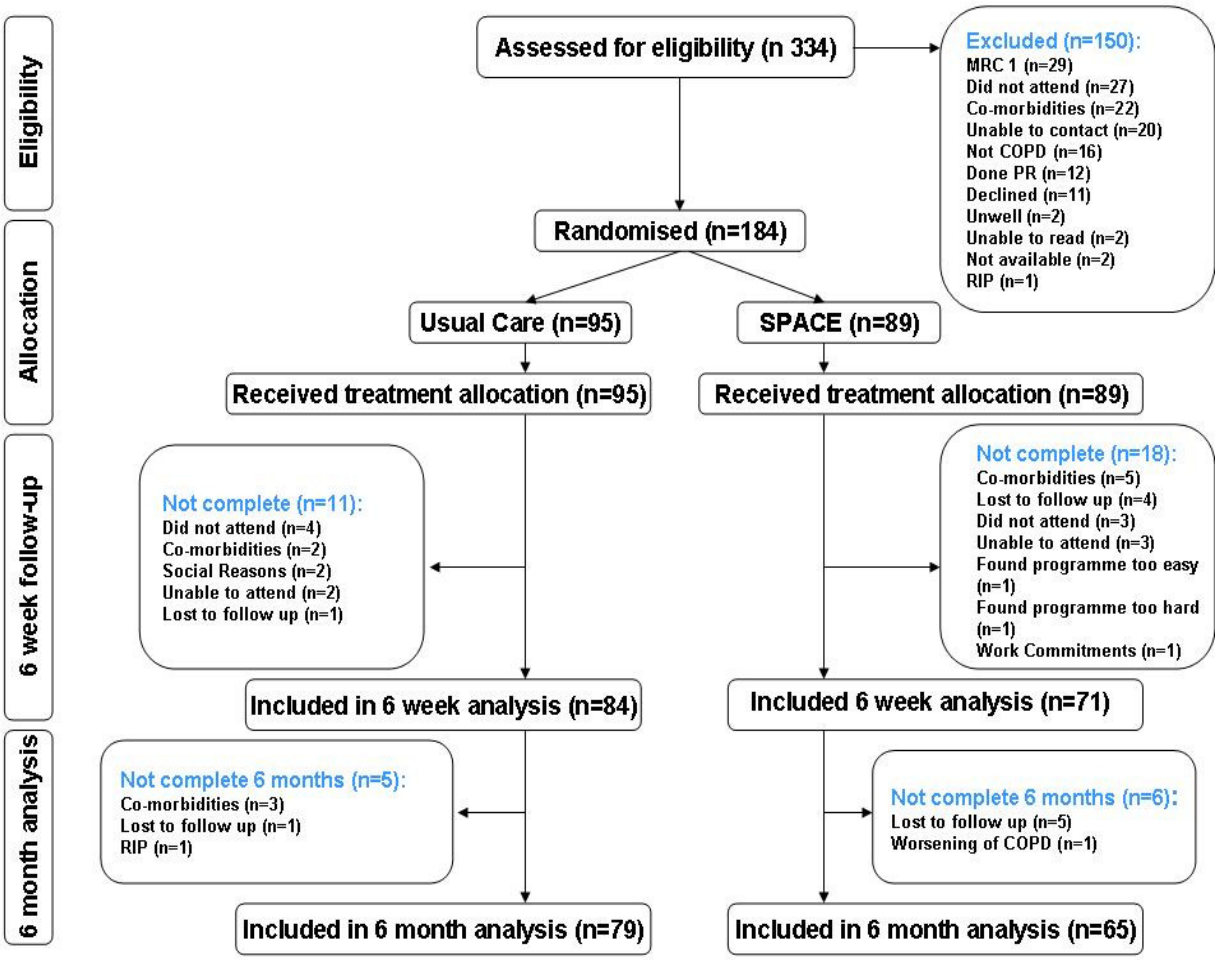
In the analysis of RCTs there may be several reasons why data may be missing or excluded from analysis, including failure to start, non-compliance, false inclusions or missing response (Hollis and Campbell 1999). An intention to treat approach (ITT) compares patients in the groups to which they were originally assigned. It has been argued to be the superior approach as it is likely to reduce bias (Lee et al. 1991), and not performing ITT analysis may lead to overestimation of the clinical effectiveness (Akl et al. 2012). These data were analysed primarily with all available data, as randomised, but only in those with an outcome. Secondary analysis was ITT, with a sensitivity analysis using multiple imputations to impute missing values. This analysis was conducted in STATA. 10 models of imputation were created based on 10 variables put into the model.

All other analyses were completed using Predictive Analytics Software (PASW) v.18. Independent t tests were carried out on demographic data and baseline characteristics between those who completed the study and those who withdrew. Missing data analysis was conducted. Data was checked for normality and outliers. A repeated measure ANOVA was applied to analyse between-group comparisons in the primary outcome and all secondary outcome data. For variables with a significant test of sphericity the Greenhouse-Geisser test was used, and for variables without significant sphericity, the test of assumed sphericity was used. Differences between groups in healthcare utilisation was analysed using a negative bi-nomial regression model.

5.4 Results

184 patients were recruited to the study, 95 were randomised to usual care and 89 to receive the SPACE FOR COPD intervention. There was no cross-over of randomisation. Following a drop out rate of 15.7% between baseline and six weeks, there was a further drop out of five patients from the usual care group and six patients from the SPACE FOR COPD group between the six-week and six-month assessments. The total drop out rate from the study was 40 patients (21.7%). This means that the minimum of 62 patients per group required for adequate power was achieved. Figure 5.1 documents the reasons for study withdrawal.

Figure 5.1 CONSORT flow diagram of patient recruitment, randomisation and reason for withdrawal



As shown in table 5.1, there were no statistically significant differences in demographic characteristics or baseline outcome measures between those who completed the study and those who did not.

Table 5.1 Baseline characteristics of completers and on-completers at six months

		Completer n=144	Non-completer n=40	p value
SPACE: Usual care [n (%)]		65 (45) : 79 (55)	24(60) :16 (40)	0.096
Male: Female [n (%)]		80(56) : 64 (44)	21 (53) :19 (47)	0.731
Age years [mean (SD)]		69.6 (9.3)	69.1 (9.0)	0.718
FEV_1 litres [mean (SD)]		1.47 (0.55)	1.36 (0.60)	0.251
BMI [mean (SD)]		27.52 (5.17)	27.68 (5.64)	0.868
CRQ-SR [mean(SD)]	**Dyspnoea**	3.17 (1.19)	2.92 (1.16)	0.264
	Fatigue	3.88 (1.27)	4.14 (1.04)	0.269
	Emotion	4.88 (1.25)	4.94 (1.13)	0.792
	Mastery	5.25 (1.36)	5.14 (1.32)	0.650
ISWT metres [mean (SD)]		340.7 (152.4)	321.8 (176.6)	0.517
ESWT seconds [mean (SD)]		262.6 (177.8)	278.0 (198.1)	0.638
HADS [mean(SD)]	**Anxiety**	6.40 (4.03)	6.24 (4.15)	0.831
	Depression	5.12 (3.17)	5.46 (3.45)	0.574
Lives with [n (%)]	**Spouse**	86 (60)	26 (65)	0.775
	Alone	33 (22)	7 (18)	
	Family	14 (10)	5 (12)	
	Other	11 (8)	2 (5)	

Intention to Treat

A test for missing data was conducted on all variables. Estimates were non-significant (p=0.686), therefore it is accepted that data is missing completely at random.

There were no failures to start the intervention, no false inclusions in these data sets and compliance could not be measured. Therefore the only requirement to perform ITT analysis was to impute missing values. The imputed values for the primary outcome all fell within the expected range.

The Primary Outcome

Repeated measures showed Mauchly's test of sphericity was significant (p=0.038) therefore the results of the Greenhouse-Geisser test were used to correct for this. Table 5.2 shows the results from the repeated measures ANOVA of the primary outcome, CRQ-SR dyspnoea score.

Table 5.2 Significance levels of within-subject effects of time and time and intervention and between-subject effects for the CRQ-SR dyspnoea score

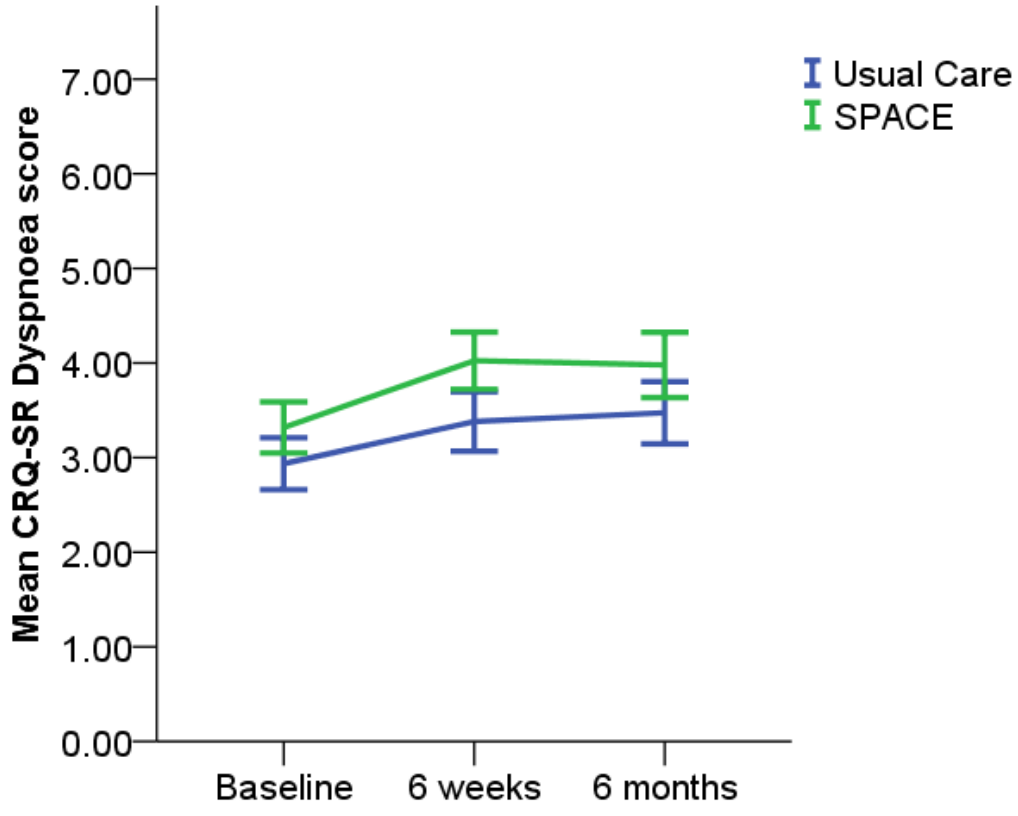
	Within-subject effects		**Between-subject effects**
	Time	**Time*Intervention**	
CRQ-SR dyspnoea	p<0.001	p=0.16	p=0.007

The mean CRQ-SR dyspnoea scores for both groups are displayed in table 5.3. These data are plotted in figure 5.2 for all time points.

Table 5.3 Mean baseline, six weeks, six months and change scores for the CRQ-SR dyspnoea domain

CRQ-SR dyspnoea score	Usual care mean (SD)	SPACE mean (SD)	Between-group difference mean (95%CI)
Baseline	2.95 (1.17)	3.31 (1.07)	0.36 (-0.09 to 0.70)
6 weeks	3.38 (1.35)	4.02 (1.19)	0.64 (0.23 to 1.09)
6 months	3.44 (1.40)	3.97 (1.37)	0.53 (-0.06 to 0.88)
Mean change (baseline to 6 months)	0.49 (1.27)	0.66 (1.07)	0.17 (-0.29 to 0.52)

Figure 5.2 Mean dyspnoea scores for SPACE FOR COPD and usual care groups at three time points



The MCID of the CRQ-SR is 0.5. Using this value, the population was dissected into 'responders' (those who changed ≥0.5 on the CRQ-SR dyspnoea score) and 'non-responders' (those who changed <0.5 on the CRQ-SR dyspnoea). The numbers of responders and non-responders per group is displayed in table 5.4.

Table 5.4 Number of responders and non-responders in SPACE FOR COPD and usual care groups measured by the CRQ-SR dyspnoea score

	Responder n (%)	**Non-responder n (%)**	**p value**
SPACE	35 (56)	28 (44)	0.173
Usual care	32 (44)	41 (56)	

These findings suggest that there were no significant differences between the groups of the impact on CRQ-SR dyspnoea domain. The significant between-subjects effect from the ANOVA is likely to be due to the difference between the groups at baseline. As a group as a whole, only the SPACE FOR COPD group exceeded the change of ≥0.5, which is the MCID.

Secondary Outcomes

HRQoL was measured by the other three domains of the CRQ-SR; fatigue, emotion and mastery. Repeated measures Mauchly's test of sphericity was significant for all three domains (p=0.041, 0.046 and 0.025 for fatigue, emotion and mastery respectively). Results from the repeated measures ANOVA are displayed in table 5.5

Table 5.5 Significance levels of within-subject effects of time and time and intervention and between-subject effects for the CRQ-SR fatigue, emotion and mastery domains

	Within-subject effects		Between-subject effects
	Time	Time*Intervention	
CRQ-SR fatigue	p=0.017	p=0.05	p=0.135
CRQ-SR emotion	p=0.122	p=0.09	p=0.218
CRQ-SR mastery	p=0.442	p=0.08	p=0.292

The mean values for the CRQ-SR domains at baseline, six weeks, six months and mean changes from baseline to six months were calculated. These are displayed in table 5.6 and plotted on figures 5.3- 5.5. Overall, this suggests that absolute HRQoL scores were maintained between six weeks and six months, however statistical significance was lost.

Table 5.6 Mean baseline, six weeks, six months and change scores for CRQ-SR fatigue, emotion and mastery domains

		SPACE mean (SD)	Usual care mean (SD)	Between-group difference mean (95%CI)
CRQ-SR fatigue score	**Baseline**	3.93 (1.23)	3.80 (1.32)	0.13 (-0.31 to 0.53)
	6 weeks	4.37 (1.15)	3.80 (1.47)	0.57 (0.07 to 0.96)
	6 months	4.12 (1.34)	3.70 (1.40)	0.42 (-0.18 to 0.22)
	Change baseline to 6 months	0.19 (1.09)	-0.12 (0.77)	0.31 (-0.12 to 0.53)
CRQ-SR emotion score	**Baseline**	4.86 (1.27)	4.83 (1.22)	0.03 (-0.31 to 0.52)
	6 weeks	5.20 (1.18)	4.75 (1.32)	0.45 (0.00 to 0.83)
	6 months	5.02 (1.32)	4.64 (1.43)	0.38 (-0.15 to 0.77)
	Change baseline to 6months	0.16 (1.18)	-0.19 (0.85)	0.35 (-0.08 to 0.60)
CRQ-SR mastery score	**Baseline**	5.25 (1.32)	5.14 (1.40)	0.11 (-0.34 to 0.56)
	6 weeks	5.40 (1.17)	5.03 (1.49)	0.37 (-0.14 to 0.76)
	6 months	5.29 (1.37)	4.91 (1.52)	0.38 (-0.20 to 0.77)
	Change baseline to months	0.04 (1.03)	-0.23 (1.05)	0.27 (-0.14 to 0.56)

Figure 5.3 Mean fatigue scores for SPACE FOR COPD and usual care at three time points

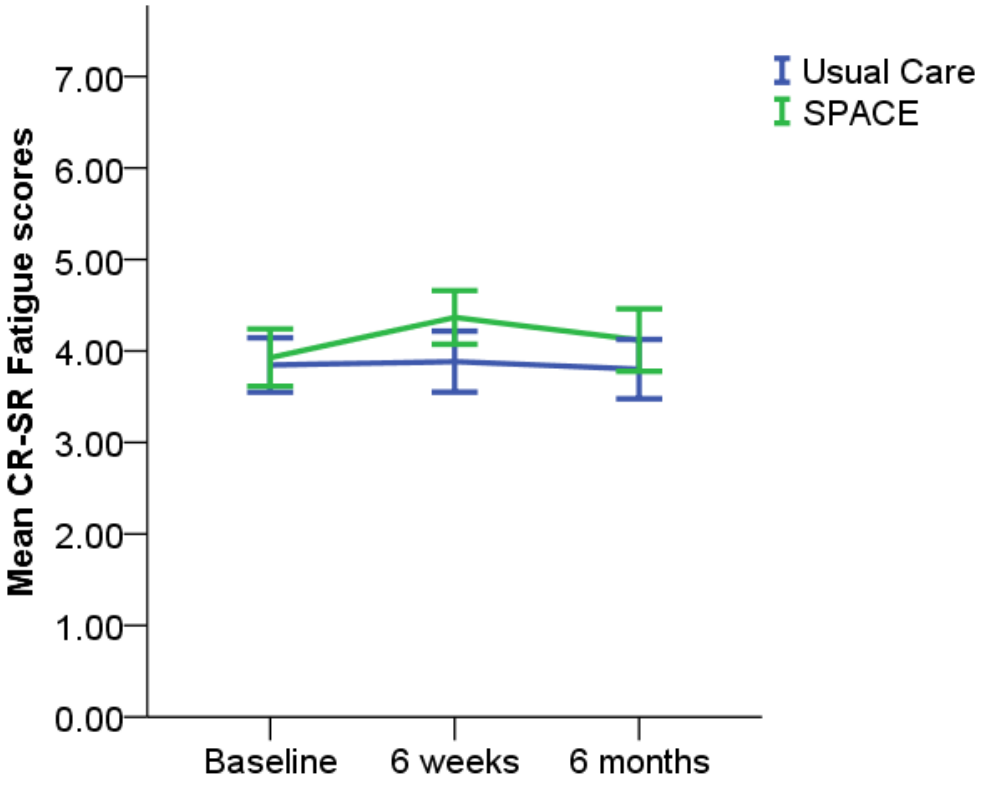


Figure 5.4 Mean emotion scores for SPACE FOR COPD and usual care at three time points

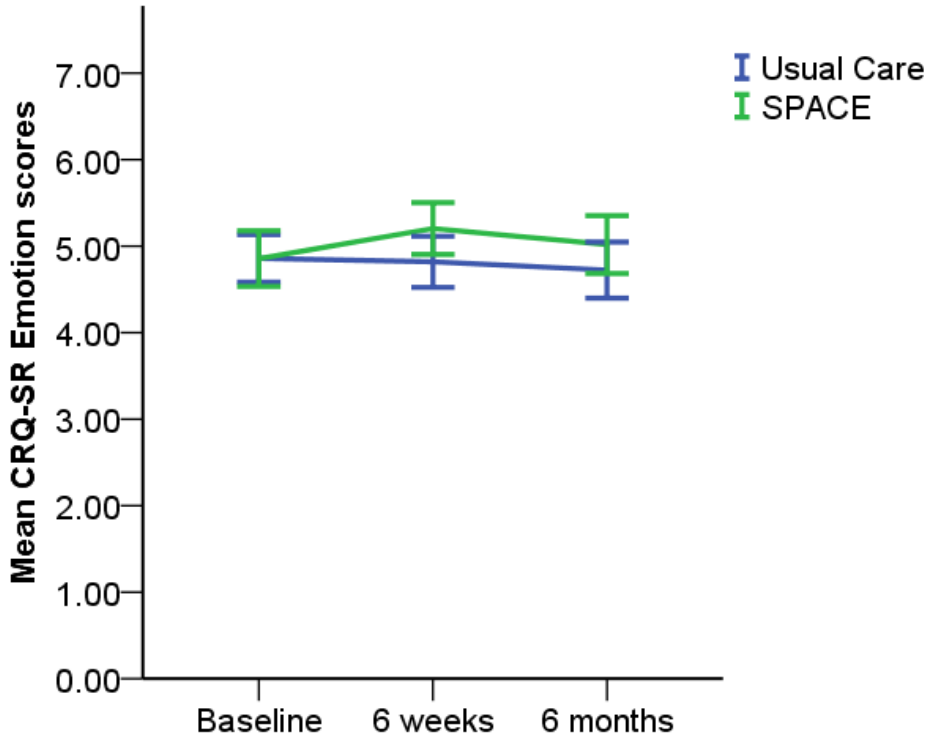
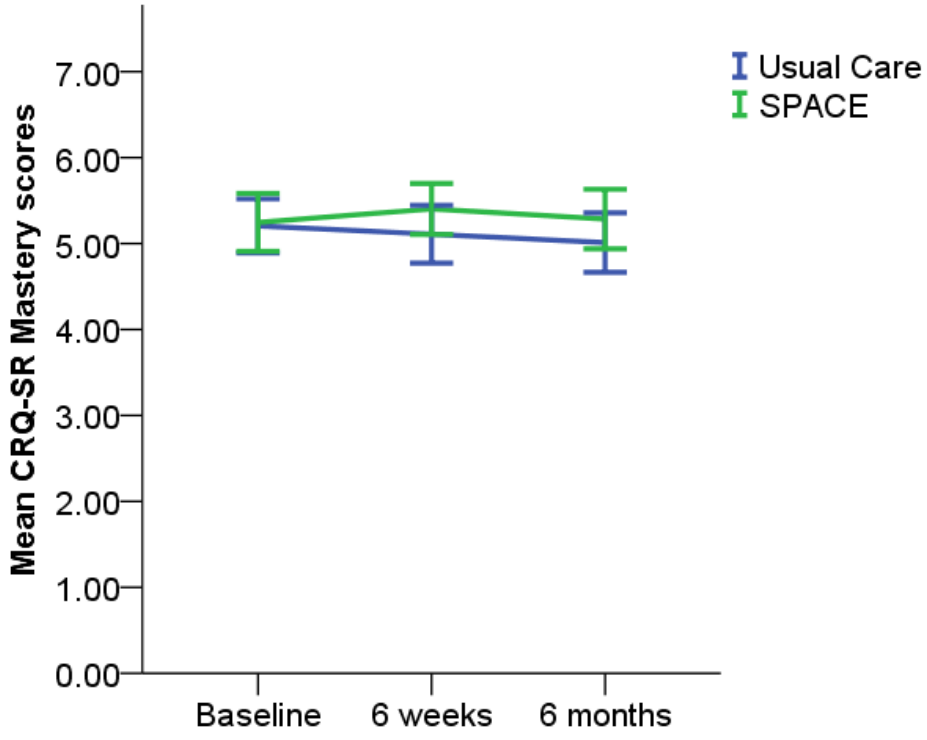


Figure 5.5 Mean mastery scores for SPACE FOR COPD and usual care at three time points



Exercise performance was measured by the ISWT and the ESWT. Mauchly's test for sphericity was not significant for the ISWT (p= 0.217) and was significant for the ESWT (p<0.001). Results from the repeated measures are displayed in table 5.7. The findings suggest that between-group differences in maintenance of ISWT between six weeks and six months were not maintained, while between-group differences in the maintenance of ESWT were.

Table 5.7 Significance levels of within-subject effects of time and time and intervention and between-subject effects for the ISWT and ESWT

	Within-subject effects		Between-subject effects
	Time	Time*Intervention	
ISWT	p=0.893	p=0.52	p=0.971
ESWT	p<0.001	p=0.03	p=0.038

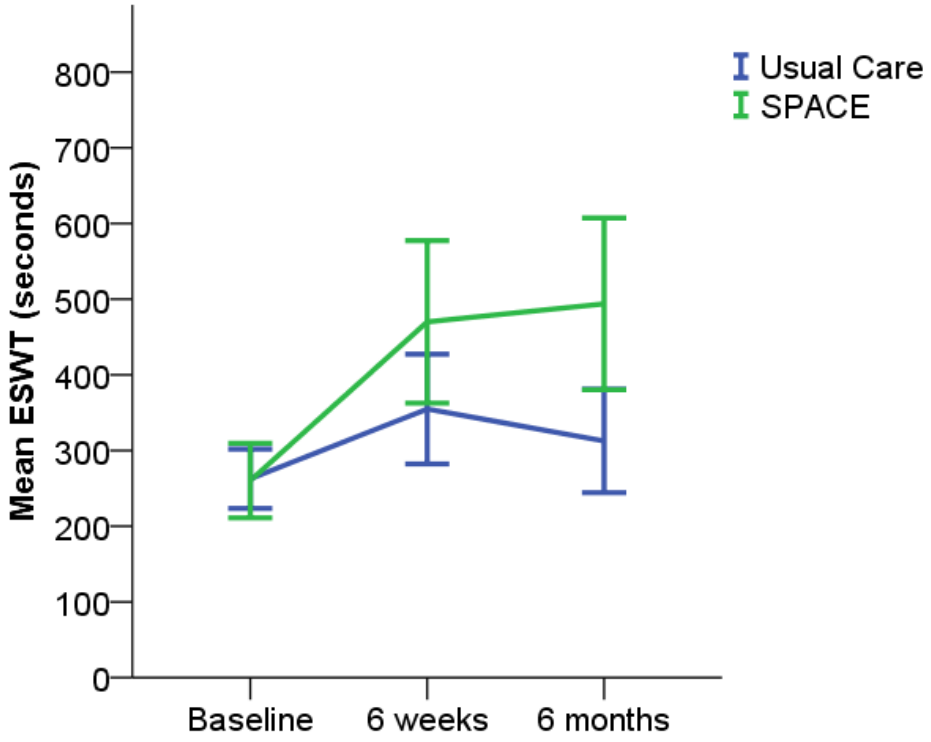
The mean baseline, six weeks, six months and change scores for the ISWT and ESWT are displayed for both groups in table 5.8.

Table 5.8 Mean baseline, six weeks, six months and change scores for the ISWT and ESWT

		SPACE mean (SD)	Usual care mean (SD)	Between-group difference mean (95%CI)
ISWT (metres)	**Baseline**	343.0 (150.0)	353.0 (161.8)	-10.0 (-80.0 to 20.8)
	6 weeks	352.8 (161.2)	346.3 (163.7)	6.5 (-58.7 to 48.0)
	6 months	353.5 (154.2)	347.3 (163.9)	6.2 (-52.7 to 61.0)
	Change baseline to 6 months	10.5 (63.3)	-5.7 (50)	16.2 (-1.7 to 38.8)
ESWT (seconds)	**Baseline**	260.3 (179.4)	262.8 (166.6)	-2.5 (-80.1 to 37.9)
	6 weeks	470.0 (390.9)	354.8 (307.5)	115.2 (-8.2 to227.1)
	6 months	493.8 (413.0)	312.6 (290.1)	181.2 (54.01 to 300.1)
	Change baseline to 6 months	233.5 (354.1)	49.8 (232.2)	183.7 (83.4 to 291.6)

The changes in ESWT over the three time points for both groups are displayed in figure 5.6.

Figure 5.6 Mean ESWT scores for SPACE FOR COPD and usual care at three time points



Anxiety and depression was measured with the HADS. Anxiety was significant on Mauchly's test of sphericity (p=0.028) while depression was not (p=0.246). Results from the repeated measures ANOVA are displayed in table 5.9.

Table 5.9 Significance levels of within-subject effects of time and time and intervention and between-subject effects for anxiety and depression

	Within-subject effects		Between-subject effects
	Time	**Time*Intervention**	
Anxiety	p=0.348	p=0.044	p=0.041
Depression	p=0.399	p=0.147	p=0.32

Mean baseline, six weeks, six months and changes scores for anxiety and depression are displayed in table 5.10. Lower scores demonstrate lower levels of anxiety/ depression.

Table 5.10 Mean baseline, six weeks, six months and change scores for anxiety and depression

		SPACE mean (SD)	**Usual care mean (SD)**	**Between-group difference mean (95%CI)**
Anxiety	**Baseline**	5.98 (3.94)	6.91 (4.06)	-0.93 (-2.45 to -0.20)
	6 weeks	5.26 (3.94)	7.03 (4.10)	-1.77 (-3.12 to 0.44)
	6 months	5.68 (4.10)	7.00 (4.19)	-1.32 (-2.74 to 0.02)
	Change baseline to 6 months	-0.30 (2.98)	0.09 (2.39)	-0.39 (-1.22 to 0.57)
Depression	**Baseline**	5.32 (3.22)	5.06 (3.10)	0.26 (-1.03 to 1.08)
	6 weeks	4.82 (3.43)	5.29 (3.38)	-0.47 (-1.63 to 0.63)
	6 months	5.13 (3.41)	5.53 (3.67)	-0.40 (-1.56 to 0.81)
	Change baseline to 6 months	-0.19 (2.68)	0.47 (2.14)	-0.66 (-1.34 to 0.31)

It has been suggested that a score of 8 or above on the HADS may be suggestive of a presence of anxiety and/ or depression (Zigmond & Snaith 1983). Given that the mean baseline scores for the group as a whole fall below this threshold, a sub-group analysis of those with a baseline score of 8 or above for each domain was performed. The mean scores for all three time points are displayed in table 5.11, and illustrated in figures 5.7 and 5.8.

Table 5.11 Mean baseline, six weeks, six months and change scores for HADS anxiety and depression for a sub-group of participants with baseline scores more than or equal to 8

		SPACE mean (SD)	Usual care mean (SD)	Between-group difference mean (95%CI)
Anxiety (n=56)	**Baseline**	10.50 (2.11)	10.67 (2.47)	-0.17 (-1.45 to 1.09)
	6 weeks	9.50 (3.11)	10.30 (2.98)	-0.80 (-2.33 to 1.10)
	6 months	9.36 (3.81)	10.18 (3.42)	-0.82 (-2.80 to 1.16)
	Change baseline to 6 months	-1.14 (2.99)	-0.52 (2.25)	-0.62 (-2.04 to 0.80)
Depression (n=35)	**Baseline**	9.44 (1.38)	9.94 (1.77)	-0.5 (-1.56 to 0.57)
	6 weeks	8.56 (3.24)	9.25 (3.53)	-0.69 (-2.79 to 1.90)
	6 months	8.00 (2.87)	10.25 (3.79)	-2.25 (-4.58 to 0.08)
	Change baseline to 6 months	-1.44 (2.43)	0.31 (2.94)	-1.75 (-3.63 to 0.12)

Figure 5.7 Mean HADS anxiety scores at three time points for the sub-group with a baseline score more than or equal to 8

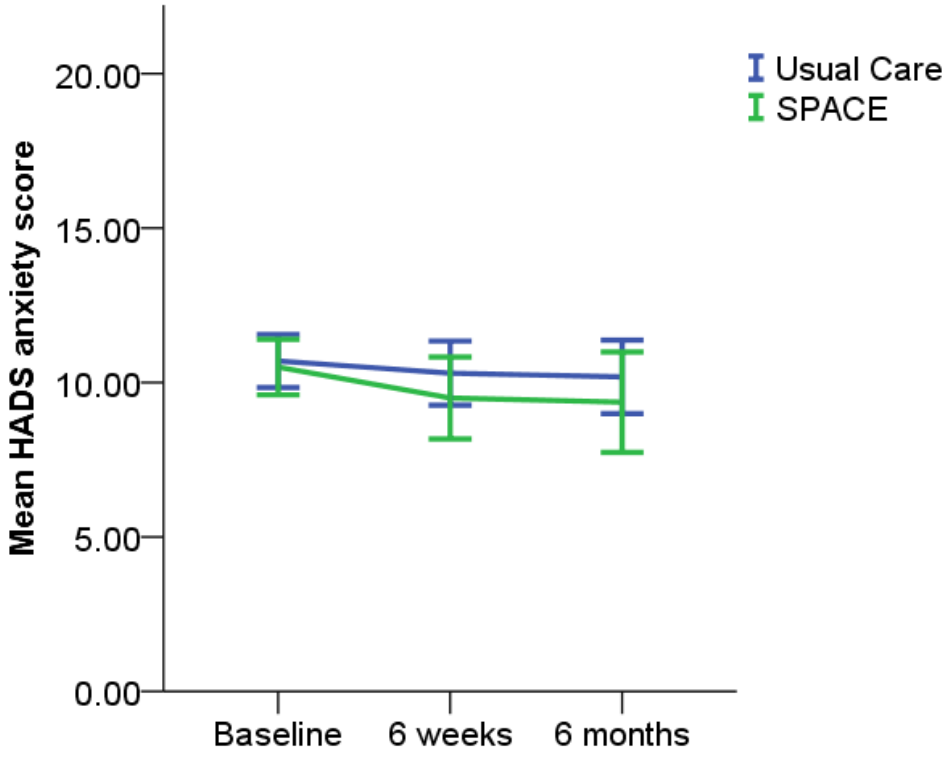
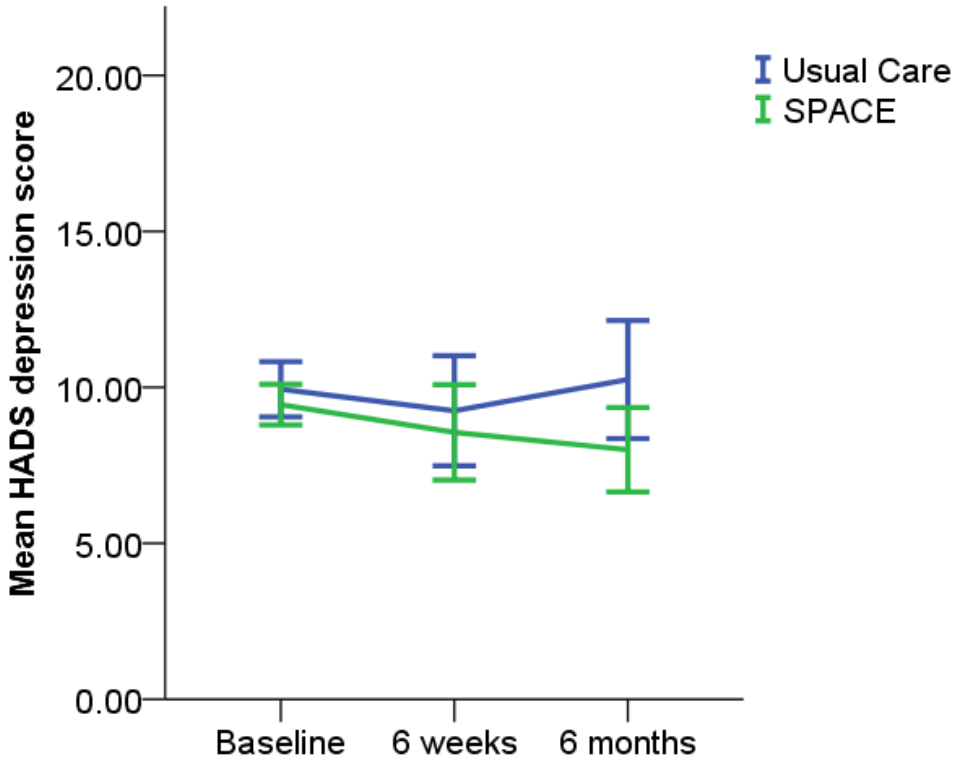


Figure 5.8 Mean HADS depression at three time points for the sub-group with a baseline score more than or equal to 8



Knowledge and self-efficacy

The results of the repeated measures ANOVA are presented in table 5.12. Mean scores for both the BCKQ and PRAISE at all three time points are displayed in table 5.13. Overall, this suggests that between-group changes in disease knowledge are maintained between six weeks and six months, although statistical significance is borderline. There were no significant changes in self-efficacy at six weeks or six months.

Table 5.12 Significance levels of within-subject effects of time and time and intervention and between-subject effects for knowledge and self-efficacy

	Within-subject effects		**Between-subject effects**
	Time	**Time*Intervention**	
BCKQ	p=0.001	p=0.05	p=0.029
PRAISE	p=0.476	p=0.20	p=0.161

Table 5.13 Mean baseline, six weeks, six months and change scores for knowledge and self-efficacy

		SPACE mean (SD)	Usual care mean (SD)	Between-group difference mean (95%CI)
BCKQ	**Baseline**	35.40 (7.57)	33.07 (10.16)	2.33 (-0.90 to 5.69)
	6 weeks	37.56 (7.76)	33.44 (10.26)	4.12 (1.13 to 7.70)
	6 months	38.02 (8.16)	34.00 (10.68)	4.02 (0.80 to 7.78)
	Change baseline to months	2.62 (6.74)	0.93 (4.90)	1.69 (0.15 to 4.96)
PRAISE	**Baseline**	46.00 (7.03)	45.17 (8.15)	0.83 (-1.91 to 3.17)
	6 weeks	46.89 (7.54)	44.29 (8.11)	2.6 (-0.16 to 5.02)
	6 months	47.10 (7.56)	44.69 (8.22)	2.41 (-0.96 to 4.44)
	Change baseline to 6 months	1.10 (5.38)	-0.48 (6.78)	1.58 (-0.79 to 3.40)

Table 5.14 Healthcare utilisation for both SPACE and usual care groups

	SPACE	Usual care	Exp (B) [95% CI]
Courses Antibiotics	82	70	1.19 (0.77 to 1.86)
Courses Steroids	22	27	0.88 (0.47 to 1.66)
GP visits (R)	78	73	1.15 (0.75 to 1.78)
GP visits (NR)	196	172	1.22 (0.86 to 1.75)
PN visits (R)	48	53	0.97 (0.60 to 1.59)
PN visits (NR)	46	48	0.97 (0.59 to 1.59)
RN home visits	10	26	0.41 (0.19 to 0.91)
ED visits (R)	1	2	0.54 (0.05 to 6.09)
ED visits (NR)	8	4	2.16 (0.63 to 7.42)
Admissions (R)	2	5	0.43 (0.08 to 2.28)
Admissions (NR)	15	21	0.77 (0.37 to 1.59)

5.5 Discussion

Following the results of the short-term outcomes discussed in chapter 4, this chapter aimed to evaluate the medium-term impact, once the formal support of the programme was complete. The main trial design was powered to detect a difference between these groups in the dyspnoea domain of the CRQ-SR at six months, and it was upon this that the hypothesis was tested. The remainder of this chapter will discuss these findings within the context of other studies, address the study limitations and draw conclusions from this work.

The primary outcome

The repeated measures ANOVA shows there is no significant difference between the SPACE FOR COPD group and the usual care group over the six-month follow-up (p= 0.16). Therefore, the hypothesis that SPACE FOR COPD would confer greater benefit on HRQoL at six months compared with usual care is rejected. The results also show a significant effect of time, regardless of randomisation (p<0.001). This means that both groups improved significantly over the six-month period. From baseline to six months the mean changes were 0.66 for the SPACE FOR COPD group and 0.49 for the usual care group. Of these mean group scores, only the SPACE FOR COPD group exceeds the MCID of 0.5. In addition, 56% of the SPACE FOR COPD group improve by at least 0.5 compared with 44% of the usual care group.

Effing et al. (2011) is one of few other RCTs of a self-management intervention that has measured the CRQ-SR at a follow up. This study was powered on the change in ISWT rather than the CRQ-SR, although they did detect a significant between-group difference on the CRQ-SR dyspnoea domain at 12 months (p=0.04). However, the actual change score from baseline was less than half of that observed in the SPACE FOR COPD group, with a mean (SE) improvement in their intervention group of 0.37 (0.13) at seven months which declined to 0.30 (0.13) at 12 months follow up. It is likely that although within-group change was less, this was statistically significant between-groups because this study did not observe an improvement in the usual care group.

Maltais et al. (2008) tested the effectiveness of the 'Living Well with COPD' programme as an alternative to conventional pulmonary rehabilitation. Although there was not a control group, the within-group change in the self-management group in CRQ-SR dyspnoea was significant after three months (mean change 0.82, $p<0.001$) and, although declined, remained significant at one year (mean change 0.62, $p<0.001$). This intervention required twice weekly supervised education for four weeks and an unsupervised programme of home exercise, with the loan of cycle equipment provided in patients' homes for three months. In contrast to both Effing et al. (2011) and Maltais et al. (2008), the SPACE FOR COPD intervention provided a single 30-45 minute introduction and two telephone calls, with no supervised training or education. This highlights how important the within-group improvement in dyspnoea gained from SPACE FOR COPD is. This will be of interest to healthcare providers who will want to provide effective self-management with minimal cost.

Bischoff more recently conducted a study in primary care in the Netherlands (Bischoff et al. 2012). It was a three arm parallel RCT comparing a self-management programme, routine monitoring and usual care. Self-management was based on the 'Living Well with COPD' programme again, supported by the practice nurse, although the exercise component of the programme was removed. There were no significant advantages on the CRQ-SR of the self-management programme compared with usual care or routine monitoring. It is interesting, that despite also being in primary care and using material from a previously positive programme that more a significant change

was not observed. Some of the key differences between this and the SPACE FOR COPD study are that SPACE FOR COPD incorporated an exercise programme, which as previously discussed, may be important for driving changes in HRQoL. Additionally, in the Bischoff et al. study, the intervention was delivered by practice nurses, whereas SPACE FOR COPD was provided by a physiotherapist with expertise in COPD and skills in motivational interviewing. The level of training of the facilitator, in both disease specific knowledge and understanding of self-management and behaviour change, may be an important in determining the effectiveness of the intervention. If SPACE FOR COPD is to be delivered nationally in primary care, there may be several challenges around training which will need to be considered.

Secondary outcomes

Health-related quality of life

Fatigue, emotion and mastery domains of the CRQ-SR are reported as other measures of HRQoL. The differences between groups at six months were not statistically significant for any of the three domains; fatigue [mean (95% CI) treatment effect 0.31 (-0.12 to 0.53) p=0.05; emotion 0.35 (-0.08 to 0.60) p=0.09; mastery 0.29 (-0.14 to 0.56) p=0.08].

Effing et al. (2011) documented mean (95% CI) between-group differences of 0.09 (-0.34 to 0.52), 0.10 (-0.22 to 0.42) and 0.11 (-0.21 to 0.43) for fatigue, emotion and mastery respectively, none of which were statistically significantly different to usual care. Bischoff et al. (2012) also failed to document any significant improvements on these domains at either six or 12 months [mean

(95% CI) treatment effect at 12 months -0.17 (-0.62 to 0.27); -0.31 (-0.66 to 0.039); -0.20 (-0.55 to 0.14) for fatigue, emotion and mastery respectively]. Maltais et al. (2008) demonstrated within-group changes in the self-management group at three months [mean (95%CI) 0.36 (0.17 to 0.55) $p<0.001$, 0.35 (0.20 to 0.50) $p<0.001$ 0.49 (0.32 to 0.66) $p<0.001$ for fatigue, emotion and mastery respectively] which all declined during the follow up at 12 months [mean (95%CI) 0.25 (0.06 to 0.44) $p=0.01$, 0.28 (0.14 to 0.43) $p<0.001$, 0.39 (0.23 to 0.57) $p<0.001$].

Out of any of these studies, the changes in HRQoL after the follow-up period were greatest in the Maltais et al. programme. This population was a similar age to SPACE FOR COPD, although slightly more severe at baseline. As previously described, in the Maltais et al. study participants were provided with supervised education and were loaned exercise bikes for the first three months. One difference which may be fundamental to the maintenance of outcomes is that the Maltais et al. study included regular telephone contact every two months by a case manager. This kind of on-going support has been identified in the Chronic Care Model (CCM) as important to sit alongside self-management (Wagner 1998). A systematic review found that the more components of the CCM that were present the better the outcomes would be (Adams et al. 2007). This suggests that on-going support, such as telephone contact, alongside self-management may be more effective. Methods of on-going support will be discussed further in chapter 8.

While the changes in HRQoL were not necessarily statistically significant at six months, the absolute changes were still greater than those of the Effing and Bischoff studies. As previously discussed, the lack of an exercise programme and the delivery of the programme from a practice nurse may be important features of the lack of improvement in the Bischoff et al. study (2012). It is remarkable, however, that between-group differences in HRQoL in SPACE FOR COPD at six months were higher than those observed in COPE II (Effing et al. 2011), considering the COPE II programme provided much more supervised, directed support than SPACE FOR COPD.

The gradients of the slopes observed in figures 5.3- 5.4 and the results reported in chapter 4, would suggest that the improvements in CRQ-SR fatigue and emotion domains, were achieved during the first six-week period. Figures 5.3- 5.5 suggest that the benefits begin to decline between six weeks and six months. This pattern is also seen in other self-management literature. Both Khdour et al. (2009) and Bourbeau et al. (2003) measured HRQoL with the SGRQ. Bourbeau et al. (2003) documented significant treatment differences in the impact and total domains after four months of a self-management intervention compared with usual care. However, between the end of the four-month intervention period and the 12-month follow-up, there was a decline in treatment effect across all SGRQ domains, and only the impact subscale remained significant (-4.7, p=0.05). The study by Khdour et al. (2009) documented a similar effect. After significant treatment differences were initially observed in the symptoms, impact and total domains, between six and 12 months treatment effects were reduced across all domains, and

only symptoms and impact were significant at 12 months (p=0.04 and p=0.03 respectively). As previously suggested, exploring various methods of on-going support may be of interest in order to establish how these outcomes can best be maintained. However, a trend across all self-management studies, is that regardless of the outcome measure used to assess quality of life, a gradual decline can be observed over time across all control groups. This suggests that, in the face of declining quality of life for patients with COPD who receive no self-management support, preventing decline in quality of life may be challenging.

Exercise performance

Maximal exercise capacity was measured by the ISWT, and sub-maximal capacity by the ESWT. There was no significant effect of time (p=0.893) or time and intervention (p=0.52) on the ISWT, with a mean between-group difference 16.2m at six months. There was a significant effect of both time (p<0.001) and time and intervention (p=0.03) on the ESWT, with a mean between-group difference of 184 seconds at six months.

The change in ESWT between groups is an interesting finding. The MCID of the ESWT has been estimated at around 186 seconds following pulmonary rehabilitation, and around 65 seconds following bronchodilation therapy (Pepin et al. 2011). The mean between-group difference of 184 seconds approaches or exceeds these benchmarks, which suggests this difference may be meaningful to patients also.

The suggestion that SPACE FOR COPD may be effective in influencing sub-maximal exercise performance but not maximal exercise performance may be reflective of the unsupervised nature of training. The exercise programme of SPACE FOR COPD was derived from a training schedule used for pulmonary rehabilitation (Calvert et al. 2011; Sewell et al. 2006) whereby a walking programme of 85% of maximal speed is prescribed. For participants in this study, the only opportunity to become familiarised with this speed was on the initial assessment, prior to randomisation, therefore patients were expected to remember what that speed was during their home training. 85% exceeds the minimal training intensity recommendation of >60 %of maximal exercise capacity for COPD (Nici et al. 2006) and although tolerable for patients (Revill et al. 1999), in rehabilitation, is usually re-enforced through supervised training (Sewell et al. 2006). Without supervision of the walking speed which patients select, given that the speed required is at their upper end, patients engaging in the SPACE FOR COPD exercise programme may be exercising sub-optimally, at a slower speed than prescribed. Sub-optimal training may explain why the improvements in sub-maximal exercise capacity were not translated into gains in maximal performance.

There are many other self-management programmes which have demonstrated no impact on walking distance at all, despite the inclusion of an exercise component (Bourbeau et al. 2003; Maltais et al. 2008; Monninkhof et al. 2003). Although Bourbeau et al. (2003) provided eight weeks of one-to-one home visits, and Maltais et al. (2008) loaned out cycle equipment for patients to keep at home, neither showed any changes on the 6MWT [mean (95% CI)

within-group change 6MWT 8 (-1 to 18) metres at three months; 0(-13 to 12) metres at 12 months (Maltais et al. 2008)]. Monninkhof et al. (2003) provided once or twice weekly supervised exercise for two years, and yet found no between-group differences in the 6MWT [mean (SD) change at 12 months -13 (7) vs. -2(5) for self-management and usual care groups respectively]. Despite these programmes providing a high level of support, no gains in walking were found. It is an important finding that despite less contact time provided on SPACE FOR COPD compared with these other studies, exercise performance was improved and maintained over six months. Therefore, not only is this 'light-touch' approach effective in improving exercise performance, but is superior when compared with more highly supervised programmes.

Both Boxall et al. (2005) and Fernandezet al. (2009) documented significant between-group differences in distance walked on the 6MWT (35m and 66m respectively). In the study by Fernandez et al. (2009), patients received 13 home visits of one-to-one supervised time with a physiotherapist. Boxall et al. (2005) provided nine home visits over 12 weeks. While these studies have shown to be effective in improving exercise performance, both utilise considerably more time and resources than SPACE FOR COPD. In the UK this is an important consideration, given the current economic climate where financial and organisational resources are constrained.

Figure 5.6 demonstrates that between six weeks and six months there was a trend for exercise performance to continue improving, or at least maintained, in the SPACE FOR COPD group. This is an important observation. Exercise

performance may be considered a surrogate marker of health behaviour change. This observation suggests that patients who receive SPACE FOR COPD engaged in health behaviours which were sustained over a six-month period. The question of how best to maintain gains from courses, such as pulmonary rehabilitation, has long been debated and there is no consensus of the optimal way of preventing decline over time. SPACE FOR COPD may be the most effective self-management programme available in sustained changes in exercise behaviour, without on-going support.

Anxiety and depression

As a group as a whole, there was a statistically significant reduction in anxiety in the SPACE FOR COPD group, compared with usual care [mean (95%CI) treatment effect -0.39 (-1.22 to 0.57) p=0.044]. There was no significant difference between groups in change in depression [mean (95% CI) treatment effect -0.66 (-1.34 to 0.31) p=0.147]. In the sub-group analyses of participants who scored ≥8 at baseline there was no significant between-group difference in anxiety [mean (95% CI) treatment effect -0.62 (-2.01 to 0.71)]. In the sub-group of patients who scored ≥8 at baseline on depression the between-group difference was not statistically significant, but did exceed the MCID of 1.5 [mean (95% CI) treatment effect -1.75 (-3.22 to 0.44)]. It is also worthwhile to observe that the data shown in figure 5.8 suggests that reduction in depression scores continues between six weeks and six months.

Despite emotional management being a key task of self-management (Corbin & Strauss 1988), only three studies have measured the impact of self-

management on anxiety and depression (Bucknall et al. 2012; Effing et al. 2011; McGeoch et al. 2006). All studies found no significant change depression, and only Bucknall and colleagues documented a change in anxiety at 12 months [mean (95% CI) treatment effect -1.06 (-2.08 to -0.03) p=0.044]. Similarly to SPACE FOR COPD, both Effing et al. (2011) and McGeoch et al. (2006) had low baseline scores for anxiety and depression in theirs samples of patients, which as group means were below the threshold of ≥8. This is in contrast to Bucknall et al. (2012) where baseline scores were much higher [mean (SD) baseline anxiety 9.7(4.6), depression 8.4 (4.0)]. It is possible that given the higher levels of anxiety and depression in the Bucknall et al. study, there was greater room for improvement in these patients. Furthermore, the patients studied by Bucknall et al. had all been admitted to hospital for their COPD and were a post exacerbation group of patients. Anxieties in patients who have been hospitalised through their condition may be quite different to the stable populations observed in the other studies.

Although the change in depression in the sub-group of those who scored ≥8 at baseline is not statistically significant, it is clinically significant. As the reduction in depression is clinically meaningful, this is an interesting finding. It becomes more interesting when we see that, unlike many other of the outcome measures in this study where changes largely occurs within the first six weeks, the reduction in depression for those who are at risk continues between six weeks and six months. This may be because, even with treatment, the effects of depression can be long lasting and make time more time before changes are evident. However, as this was a sub-group and

included small numbers (n=35) it is unlikely to be adequately powered. As such, it would be interesting to explore this finding further in future work with sufficient power.

Healthcare utilisation

On the whole, there was no significant impact of SPACE FOR COPD on healthcare utilisation over the six month study period. While some other self-management programmes have shown a reduction in healthcare utilisation, this was not seen in the present trial (Bourbeau et al. 2003; Kdhour et al. 2009). An interesting comparison between the studies is that healthcare utilisation in the present trial is considerably lower than seen in the others. For example, there were only 7 respiratory related admissions within 6 months between all 184 participants of this trial. This is in contrast to the Bourbeau study which had 189 respiratory admissions with a year and the Khdour study which had 49 respiratory admissions over 6 months, with similar numbers of patients. It is likely that this reflects the recruitment source of the participants, with the present study having recruited from primary compared with other studies which recruited patients engaged in secondary care.

It is also important to remember that if patients' self-management improves, this may not necessarily lead to reduced healthcare utilisation. Effective self-management means the patient engages with their healthcare team *appropriately*, and improved disease knowledge and self-monitoring may potentially result in increased interaction with healthcare professionals.

Limitations

In the interpretation of these findings it is necessary to consider several limitations of this study. Firstly, as identified in the previous chapter, there was a significant improvement in the primary outcome in both the intervention and control groups of this study. At six months, the CRQ-SR dyspnoea domain was the only outcome which had improved in the usual care group. There may be several explanations of this observation, and these will be discussed further in chapter 8.

Given that this sample was a relatively milder and less severe group of patients, the generalisability of these findings are restricted to a similar population. The impact of SPACE FOR COPD on more severe, more functionally impaired patients cannot be established from these data. It is possible that more severe patients have more room for improvement and therefore greater effectiveness may be observed. Alternatively, perhaps the 'light-touch' approach of SPACE FOR COPD may not be suitable for more severe patients who may require more support in the development of their self-management skills. Evaluating SPACE FOR COPD in a group of more severe patients is warranted in the future.

Given that randomisation occurred at the patient level, there is a possibility that there may have been some treatment contamination at the GP level. It is possible that some patients may have shown the SPACE FOR COPD manual to their GP, who in turn might have described some of its content or promoted it to patients on the study who were in the usual care arm. Given that overall

there were relatively few respiratory related GP visits, it is likely that this risk was low. However, if this did occur then it may have contributed to the improvement seen in the usual care group. In the future, a cluster based randomised controlled trial which randomises at the level of the GP will control for this risk.

In evaluating the effectiveness of SPACE FOR COPD this chapter has focused on the quantitative aspects of the study. In order to appreciate the wider implications and impact of the programme both qualitative work and healthcare utilisation analysis are required. While these aspects of the study are being conducted, they did not fall within the remit of this thesis, which intended to address the impact on the clinical outcomes of the trial.

Finally, while this has been a 'proof of concept' study to establish the effectiveness of SPACE FOR COPD, it has been confined to a research environment. This is to say that, SPACE FOR COPD delivered as part of a research trial may not perform the same as when delivered as part of routine clinical service. Firstly, this study is open to selection bias, whereby patients that have been included have self-selected to be part of the trial. They may, therefore, have been a more motivated group. In usual care, not all patients may be as motivated or willing to undertake the programme, which may have an important impact on outcomes given the nature of the intervention. Additionally, in this study SPACE FOR COPD was provided by a physiotherapist with expertise in COPD and skills in motivational interviewing. It would not be expected that in usual primary care in the UK that all

healthcare professionals would have the same degree of knowledge or skill. Training in how to deliver SPACE FOR COPD must be made available, and quality assurance that it is delivered to an appropriate standard in order to optimise the programme's effectiveness as part of a normal part of clinical service.

Areas for further research

As already discussed, qualitative evaluation of this project is also in place and work on these is on-going. The findings of this evaluation will support the quantitative findings of this chapter.

While the findings of this chapter suggest that some outcomes are maintained, others decline between six weeks and six months. As suggested in the CCM, it may be important to ally self-management with on-going support for an impact on long-term outcomes. Future research should investigate the impact of on-going regular contact with a healthcare professional in conjunction with SPACE FOR COPD on the maintenance of health outcomes. There may be several methods of providing support, and this will be discussed in more detail in chapter 8.

Finally, an evaluation of SPACE FOR COPD delivered as part of routine clinical care is now warranted. These findings have given sufficient confidence that SPACE FOR COPD does confer significant benefits over and above usual care. The next stage is to deliver the programme to more patients, and within a clinical context and in less of a research trial environment. This will

allow us to establish the effectiveness of SPACE FOR COPD once selection bias of he patients is minimised and to evaluate how well it can be delivered by non-specialist healthcare professionals. A cluster-based RCT of General Practices, with training provided to practice nurses would be a suitable approach to take for such an evaluation.

Conclusions

This chapter presents and discusses the findings of an RCT to assess the effectiveness of SPACE FOR COPD compared with usual care in a population of patients with COPD in primary care. The hypothesis was that SPACE FOR COPD would confer greater gains in HRQoL at six months, compared with usual care alone. The CRQ-SR dyspnoea domain was the primary outcome, and was not significantly different between groups, therefore the hypothesis is rejected.

A number of secondary measures were taken, including quality of life, exercise performance, anxiety and depression, knowledge and self-efficacy. Significant between-group differences were observed for ESWT and anxiety at six months. Furthermore, for those at risk of depression at baseline there was a non-significant between-group change which exceeded the MCID. While absolute changes were largely maintained between six weeks and six months in many outcomes, statistical significance was lost. These findings suggest that there is some impact of SPACE FOR COPD compared with usual care alone, although more support may be required to maintain some of the outcomes.

A feature of SPACE FOR COPD that may be important for maintenance may be the 'light-touch' approach of the programme. If patients can learn how to self-manage their COPD independently at home, within the environment within which they are to continue, this may have important implications for the maintenance of outcomes such as exercise performance. Participants of other programmes which provide supervised training (Boxall et al. 2005; Effing et al. 2011;Monninkhof et al. 2003), or loan exercise equipment (Maltais et al. 2008) have the disadvantage that once the method of training is removed, patients must find alternative means. Intuitively one might anticipate maintenance might be more easily achieved by commencing training by the same method by which it will be continued. Furthermore, independent learning may have a powerful impact on the empowerment of the individual which may encourage development of self-management skills.

Chapter 6 Physical activity in a population of people with COPD managed in primary care.

6.1 Introduction

In the early 20th century, bed rest was prescribed as a frontline course of treatment for many health conditions. The perception that 'rest was best' was confronted in the landmark work carried out by Jerry Morris (Morris and Crawford 1958). He found that risk of cardiovascular disease was higher for the sedentary bus drivers than for their more physically active bus conductor counterparts (Morris and Crawford 1958). Since then an increasing interest in physical inactivity and health has developed. Physical inactivity is now recognised as a pandemic (Kohl et al. 2012). The effect of physical inactivity on non-communicable diseases may be responsible for around 5.3 million deaths per year, putting it in a similar risk bracket to smoking (Lee et al. 2012).

The evidence that physical activity is reduced in people with COPD is compelling. Watz et al. (2009) showed that physical activity declined with more severe airflow limitation. Extensive work by Garcia-Aymerich and colleagues has identified that physical inactivity is associated with increased risk of hospital admission and death (Garcia-Aymerich et al. 2006). Furthermore, they later showed that while being physically active is associated with reduced lung function decline and better functional status (Garcia-Aymerich et al. 2009). Whilst the symptoms of COPD suggest that

physical inactivity is a likely consequence of COPD, there has been debate in the literature as to whether poor physical activity may in fact be a driving force behind the onset of the disease (Hopkinson and Polkey 2010). The answer to this debate, as yet, remains unresolved.

Many studies of activity in COPD have been of patients recruited through secondary care services. Until now, there have been no reports of physical activity in patients with COPD who are managed primarily in primary care. This group of patients may be unique insofar that they are disproportionately low users of healthcare, with relatively well preserved functional status given their level of airway obstruction. If it is possible to identify distinctive features of this group then it may help to explain why some patients maintain health status better than others in the face of similar airflow limitation. Given the associations between physical inactivity and health status previously identified, examining the activity levels of this population might be of particular value.

As well as analysing the physical activity of a cohort of patients from primary care, it may be of interest to interrogate the data further by testing whether there are differences in activity across disease severity. Watz et al. (2009) have demonstrated that physical activity declines with GOLD stage and MRC grade in their sample of a research cohort. This, however, has not been tested in a primary care population before.

There are no standardised approaches to measuring or reporting physical activity. Accelerometers have been used for some time to assess activity across a variety of populations. Compared with self-report physical activity, an advantage of accelerometers is that they are an objective measure and therefore not prone to reporter bias. However, the data produced from these monitors may be difficult to interpret. Looking at mean values of the output is challenging, given the large standard deviations of the data (Ng 2012). Step count has been a traditional measure of physical activity, however a recent study has shown that although most people with COPD might walk more than 30 minutes per day, this does not mean they are active, since less than 25% of their time is spent in moderate activity as measured by METs (Vitorasso et al. 2012).

The ACSM guidelines recommend that adults should spend 30 minutes, five times per week in moderate activity, and each 30 minutes should be comprised of at least 10 minutes continuous bouts (Nelson et al. 2007). Many accelerometers are able to detect that 30 minutes throughout the day has been achieved, but establishing *how* this activity was accumulated, i.e. in 10 minute bouts, is more challenging. A recent study which recruited patients from a tertiary hospital in Spain analysed bouts of light, moderate and intense activities in a sample of people with COPD [n=177 mean (SD) age 71(8) years; FEV_1 % predicted 52(16)]. Moderate was defined as a threshold of 2.6 METs, which was equivalent to 50% of the maximum oxygen consumption on an incremental test. The median number of bouts of moderate-intense activity per day was 2.6 and the median duration per bout was around 20 minutes.

Using 2.6 METs as the threshold for moderate activity, 61% of the sample met the criteria for the ACSM guidelines. When using the traditional 3 METs as the threshold for moderate activity, 50% of the population met the ACSM guidelines. This is the first study of this kind, and it necessary to perform a similar method of analysis in other populations to confirm these findings. Additionally, this study did not compare activity which was performed in ≥10 minute bouts with activity that was performed in bouts <10 minutes. It would be useful to make this comparison in this population, as it is likely that for some people with COPD activity in bouts of 10 minutes or more are not achievable.

6.2 Aims

This chapter explores the baseline physical activity data from the trial described in chapter 3 of this thesis. There were two key aims of these analyses:

ii) To describe the physical activity levels of a sample of people with COPD who are managed in primary care.

iii) To use physical activity monitoring to establish adherence to the physical activity recommendations.

6.3 Methods

For a detailed account of the methodology used please refer to chapter 3. The data described in this chapter examined the demographics and outcome measures that were observed at baseline only. Physical activity at the six-week and six-month time points is discussed in chapter 7.

Participants

As this chapter only examined baseline data, all participants of the trial were eligible for analysis.

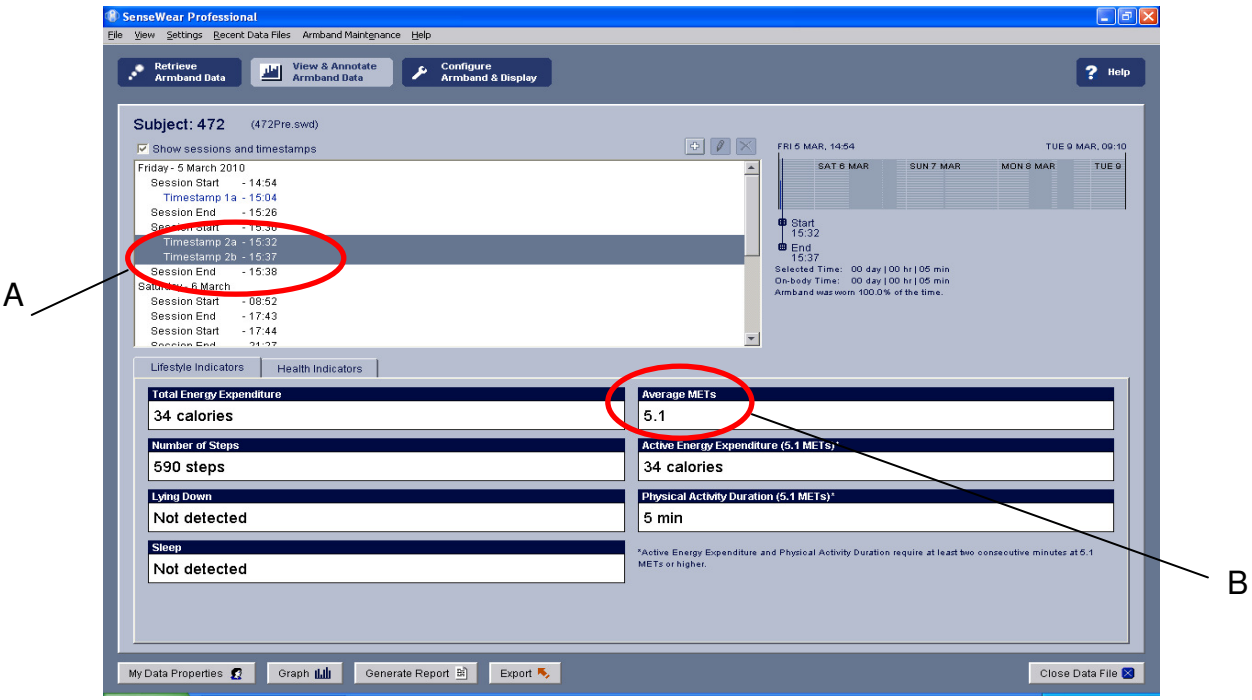
Outcome measures and variables

This chapter will primarily examine the physical activity measured at the baseline assessment of patients enrolled in the trial. Physical activity was measured with the SenseWear Pro3 ArmBand (SAB). Patients were asked to wear the monitor during waking hours for seven days. The monitor was only to be taken off at night and while showering, bathing or swimming.

Activity over exercise prescription

The monitor was also worn during the Endurance Shuttle Walking Test (ESWT) that was performed on the baseline study visit. The timestamp on the monitor was pressed at the start and end of the test. When the data from the device was analysed, the time-stamps allowed the activity data recorded during the test to be analysed. The average MET level achieved during this test identified the MET level required for an individual to exert themselves at 85% of their maximum. Figure 6.1 shows the output downloaded from an activity monitor. Circle A shows that the time selected is between the time stamp 2a (demarking the start of the ESWT) and time stamp 2b (demarking the end of the ESWT). Circle B shows the average MET level achieved during this period (5.1 in this example).

Figure 6.1 Output from SenseWear Armband during ESWT



Using this level as a benchmark, it was possible to measure the time and energy expended that breeched this threshold over the following week of wear. These data are expressed in this chapter as 'time over prescribed METs' and 'energy expenditure over prescribed METs'.

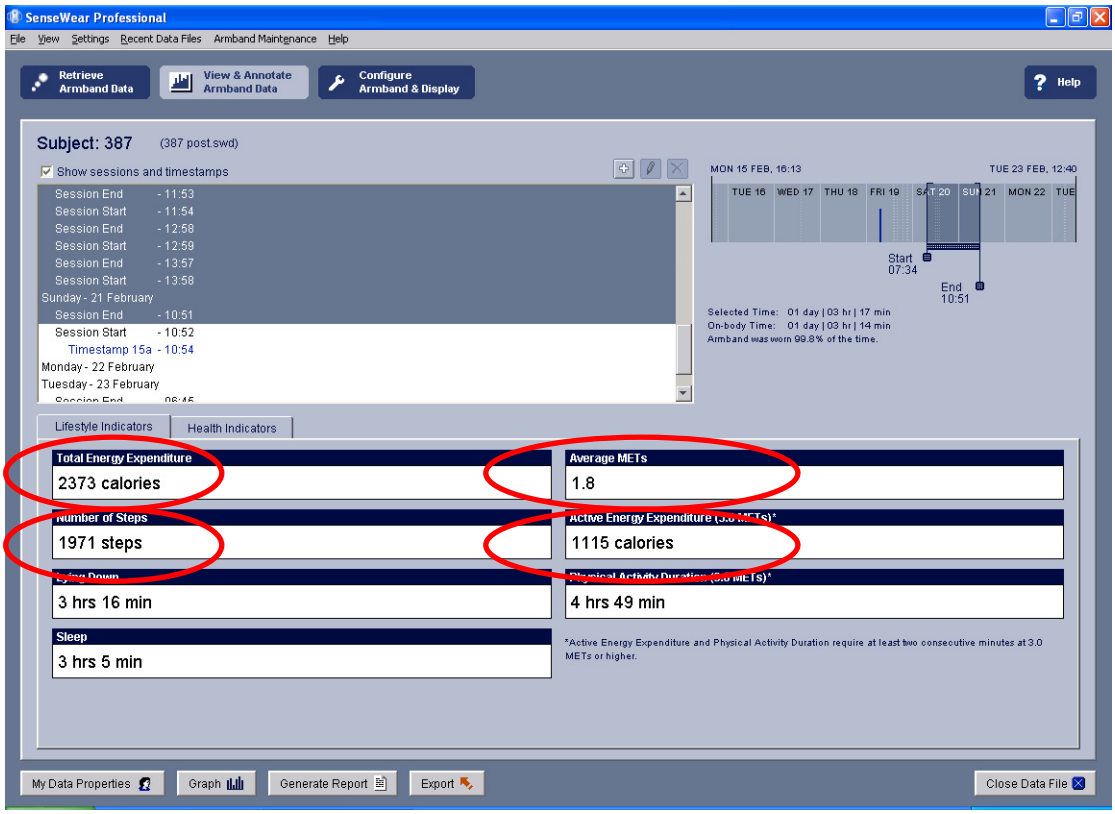
Basic monitor variables

With the basic level of SenseWear software the monitor produces several variables. These are:

- Total daily energy expenditure [TEE (Kcals)]
- Steps (n)
- Time spent over predicted METs (minutes)
- Energy expenditure (EE) over predicted METs (Kcals)

An example of this output is shown in figure 6.2.

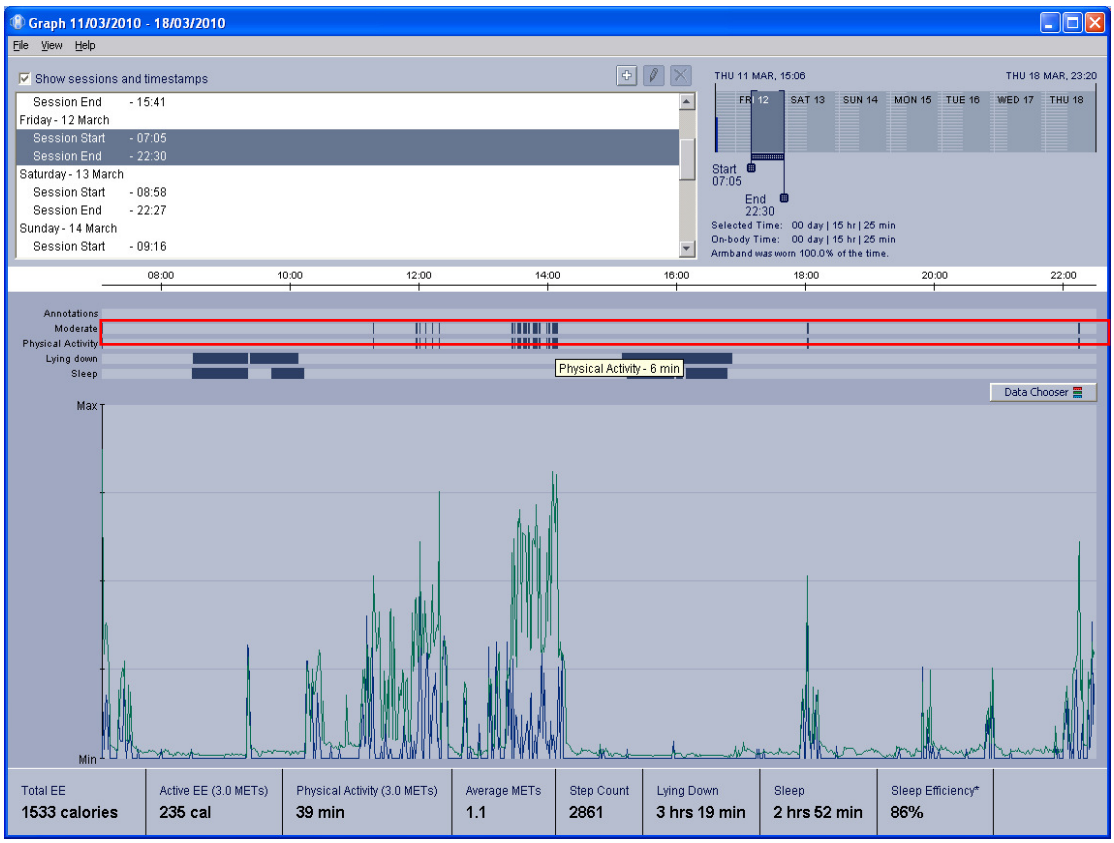
Figure 6.2 Output from the SenseWear Armband



Moderate physical activity

With advanced software for the SAB it is possible to explore how often and for how long a threshold of activity is breeched. Figure 6.3 shows an example of output for an individual during one day of wear. The bar which is highlighted, called ‘physical activity’ demarks every point in time when that individual has been active above a threshold of 3 METs. From this it is possible to observe how often and for what duration an individual exerted themselves over 3 METs. These counts were made for each individual over all seven days, and the frequency of each duration over 3 METs was logged.

Figure 6.3 Advanced output from the SenseWear Armband



The Physical Activity Level

The physical activity level (PAL), defined by the World Health Organisation, is another method of classifying physical activity. The PAL is calculated by the following equation:

$$\text{PAL} = \frac{\text{total daily energy expenditure}}{\text{basal metabolic rate}}$$

The PAL was predicted for this population by using the total daily energy expenditure predicted by the SenseWear Armband and using the Harris-Benedict equation to predict basal metabolic rate (Harris and Benedict 1918).

Thresholds of activity intensity for the PAL have been suggested and are described below (Food and Agriculture Organization 2001):

- PAL <1.4 = Extremely sedentary
- PAL 1.4 – 1.69 = Sedentary
- PAL 1.70 – 1.99 = Moderate
- PAL 2.00 – 2.40 = Vigorous
- PAL >2.40 = Extremely vigorous

Missing and excluded data

Data were excluded under any of the following conditions:

- Error message displayed while downloading monitor data
- The monitor was worn < 3 days
- Days were excluded when worn < 12 hours

All other available data was included for analysis. No attempt to impute missing data was made.

Statistical Analysis

Baseline characteristics of the population were described, and differences between participants included in activity monitor analysis and those not included were checked using independent t tests for parametric data and chi square for non-normally distributed data.

A Kruskal-Wallis test was used to test for significant differences in basic monitor variables across MRC grades and GOLD stages, and Mann-Whitney

U used for post hoc analysis. Total time spent above 3 METs and time above 3 METs in bouts of at least 10 minutes were compared with a related samples Wilcoxon signed rank test.

6.4 Results

184 patients were eligible for analysis. There was no activity monitor data available for 12 patients as the monitor had not been worn. 10 participants were excluded from analysis because the monitor was worn for less than three days. 10 data sets were removed because of activity monitor failure on downloading of data. This left 152 participants available for analysis.

Table 6.1 Baseline characteristics of participants included and not included in physical activity measurement

		Included (n=152)	Not included (n=32)	p value
Male: Female [n (%)]		85 (56) : 67 (44)	16 (50) :16 (50)	0.541
Age [mean (SD)]		69.8 (9.4)	68.3 (8.1)	0.429
FEV_1 [mean (SD)]		1.47 (0.55)	1.36 (0.60)	0.325
BMI [mean (SD)]		27.44 (5.35)	28.10 (4.83)	0.524
CRQ-SR [mean(SD)]	**Dyspnoea**	3.17 (1.14)	2.86 (1.39)	0.195
	Fatigue	3.98 (1.22)	3.74 (1.28)	0.339
	Emotion	4.96 (1.19)	4.60 (1.35)	0.145
	Mastery	5.28 (1.32)	4.94 (1.46)	0.202
ISWT m [mean (SD)]		339.6 (152.8)	319.3 (180.4)	0.511
ESWT seconds [mean (SD)]		270.8 (174.2)	242.9 (216.9)	0.432
HADS [mean(SD)]	**Anxiety**	6.07 (3.92)	7.84 (4.34)	0.026
	Depression	5.03 (3.14)	5.97 (3.54)	0.142
MRC [n (%)]:				0.396
2		85 (56)	13 (40)	
3		37 (24)	9 (28)	
4		20 (13)	7 (22)	
5		10 (7)	3 (10)	
Employment [n (%)]:				0.669
Full time		13 (8.5)	3 (9)	
Part time		10 (7)	1 (3)	
Retired		122 (80)	25 (76)	
Retired – ill health		6 (4)	2 (6)	
Sick leave		0.5	1 (3)	

How does activity vary between disease and symptom severity?

The median (IQR) values for the total daily energy expenditure, energy expenditure and time above the prescribed METs level, steps and PAL for each MRC grade are displayed in table 6.2, along with the result of the Kruskal-Wallis. Post hoc tests were only performed on the measures which had a significant result from the Kruskal-Wallis. The results of the post-hoc Man Whitney U tests are displayed in figures 6.4 and 6.5. Only significant differences are highlighted in the figures, and unless otherwise stated, differences between grades should be assumed to be non-significant.

Table 6.2 Basic monitor variables across the MRC grades

	MRC Dyspnoea Grade [median (IQR)]				Kruskal-Wallis (p value)
	2 (n=85)	3 (n=37)	4 (n=20)	5 (n=10)	
TEE (Kcals)	1353.86 (1123.57-1639.29)	1335.87 (111.87-1589.29)	1267.57 (1080.71-1450.79)	996.14 (830.21-1296.76)	0.047
EE over MET (Kcals)	70.25 (29.57-153.33)	94.57 (23.71-277.79)	129.76 (43.41-287.04)	65.63 (23.36-248.25)	0.447
Time over MET (minutes)	12.50 (4.71-26.57)	18.20 (3.86-57.06)	23.36 (8.43-74.16)	9.57 (4.77-72.39)	0.185
Steps (n)	5307 (3427-7253)	4623 (2896-6818)	3170 (1533-5817)	1659 (1239-3501)	<0.001
PAL	1.65 (1.23-2.12)	1.55 (1.16-2.40)	1.67 (1.15-2.78)	0.99 (0.90-1.04)	0.002

Figure 6.4 Steps across the MRC grades

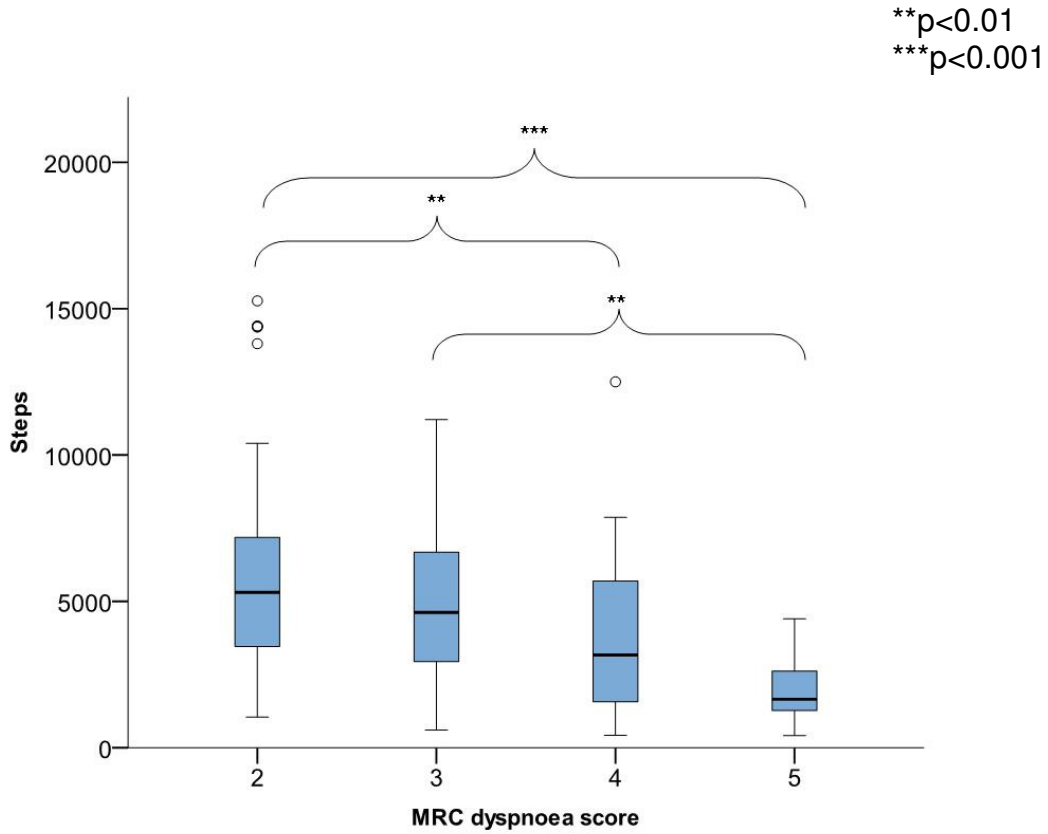
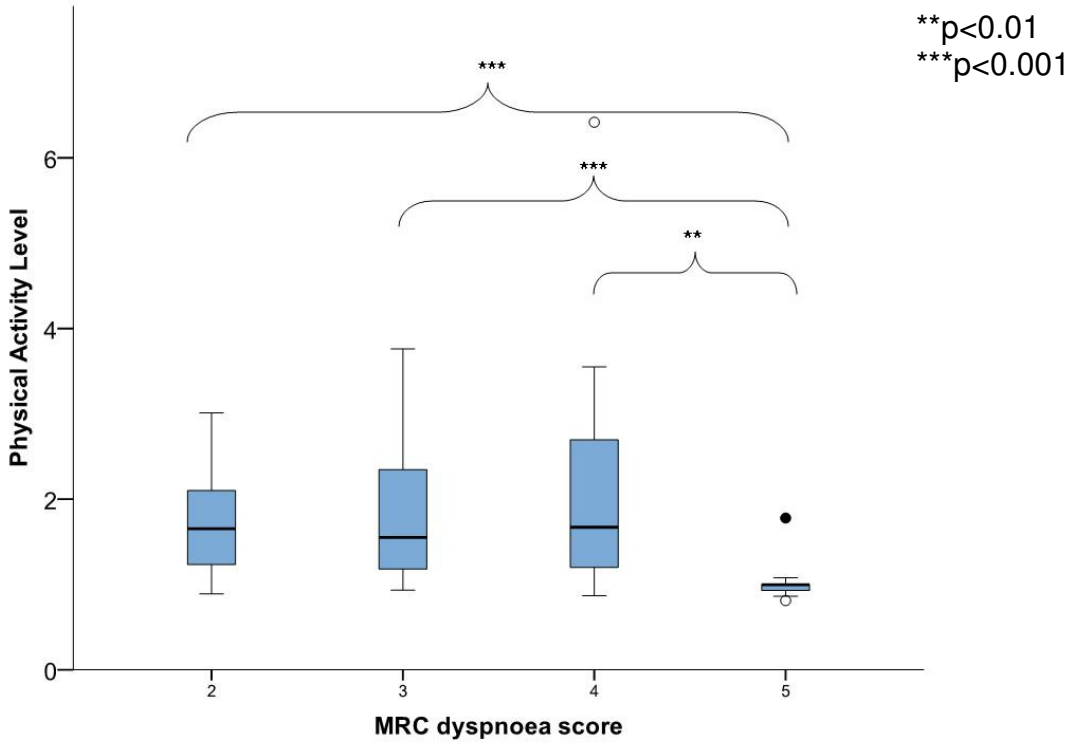


Figure 6.5 Physical Activity Level across the MRC grades



The total daily energy expenditure, energy expenditure and time above the prescribed METs level, steps and PAL for each GOLD stage are displayed in figures 6.3 and 6.4. The median (IQR) values and the results of the Kruskal-Wallis are described in table 6.3. The results of the post-hoc Man Whitney U tests are displayed in figures 6.6 and 6.7. Only significant differences are highlighted in the figures, and unless otherwise stated, differences between grades should be assumed to be non-significant.

Table 6.3 Basic monitor variables across the GOLD stages

	GOLD Stage [median (IQR)]				Kruskal-Wallis (p value)
	1 (n=12)	2 (n=95)	3 (n=33)	4 (n=11)	
TEE (Kcals)	1330.79 (1136.02-1552.21)	1349.43 (1127.61-1603.87)	1264.29 (1094.96-1582.37)	1211.14 (886.00-1362.75)	0.767
EE over MET (Kcals)	66.57 (42.42-177.03)	70.25 (21.86-159.75)	100.43 (51.57-233.50)	74.03 (57.20-406.04)	0.337
Time over MET (minutes)	10.92 (4.86-65.51)	11.28 (3.50-29.50)	20.78 (9.03-39.32)	17.91 (10.00-84.45)	0.212
Steps (n)	3597 (2607-6037)	5278 (3317-7184)	3482 (2053-6313)	4032 (1494-4392)	0.038
PAL	1.56 (1.06 - 2.16)	1.41 (1.15-2.12)	1.75 (1.22-2.28)	2.05 (1.36-2.91)	0.030

Figure 6.6 Steps across the GOLD stages

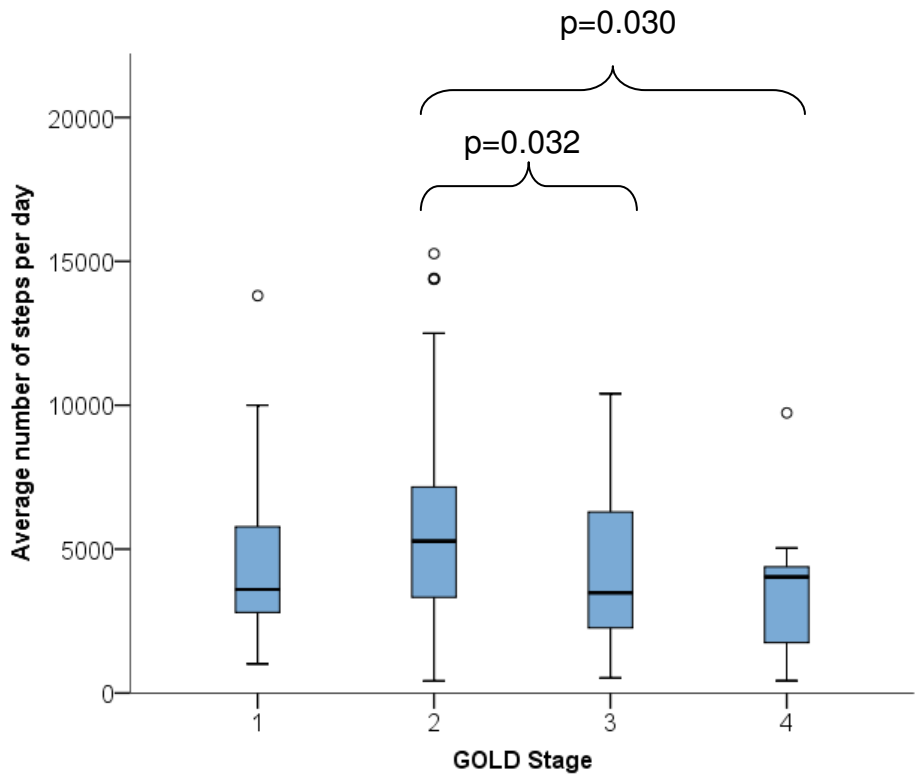
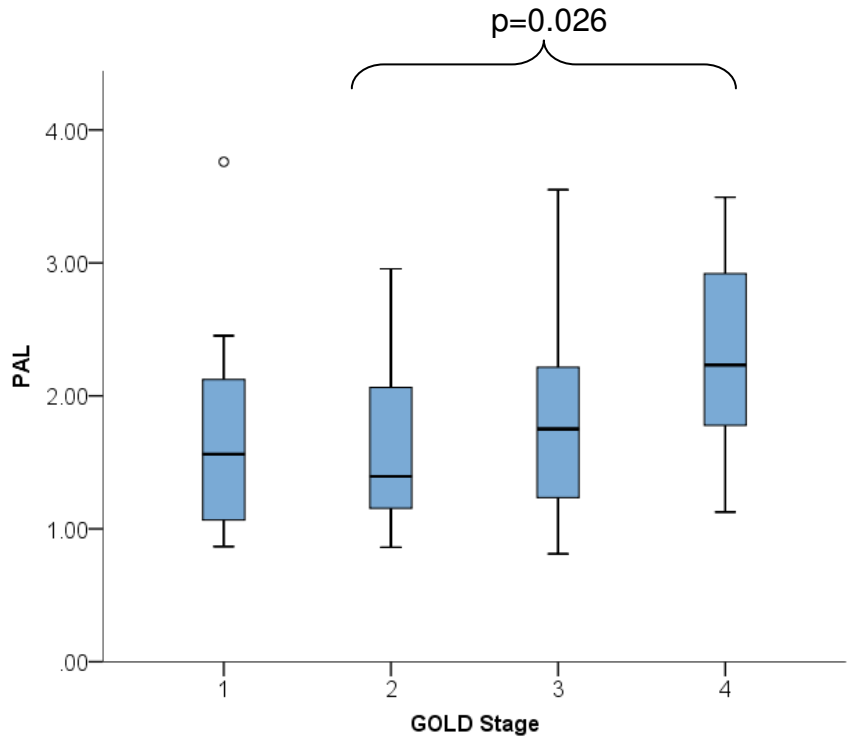


Figure 6.7 Physical Activity Level across the GOLD stages



How active is a cohort of patients in primary care?

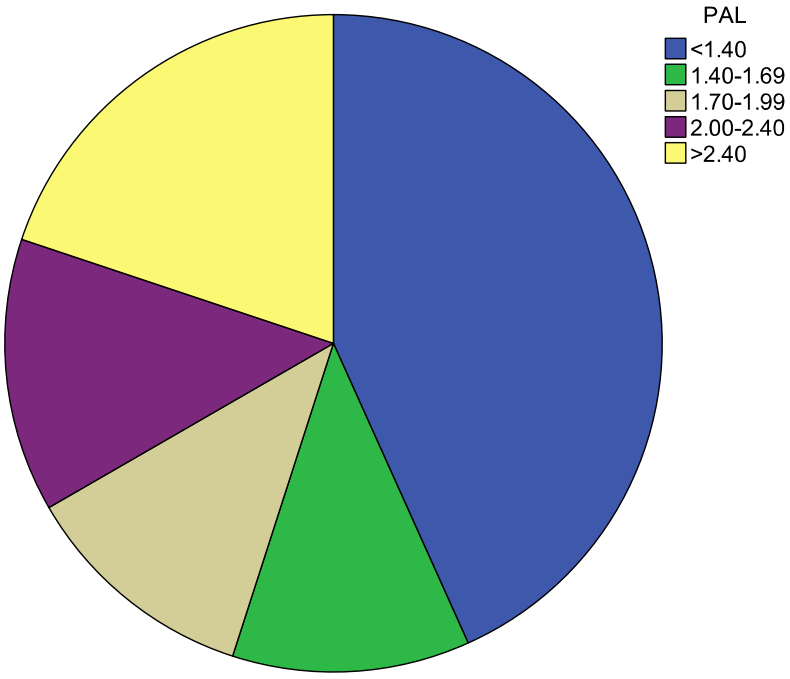
The total daily energy expenditure, energy expenditure and time above the prescribed METs level, steps and PAL are described in table 6.4.

Table 6.4 Basic monitor variables for the population at baseline

Total Daily Energy Expenditure (Kcal) [mean (SD)]	1381.34 (386.24)
Energy Expenditure over prescribed METs (Kcal) [median (IQR)]	71.43 (35.00-178.43)
Time over prescribed METs (minutes) [median (IQR)]	12.71 (5.0-33.71)
Steps (n) [mean (SD)]	5174.10 (3129.22)
PAL [mean (SD)]	1.76 (0.78)

Figure 6.8 displays the proportion of the sample that fall within the five categories of the PAL.

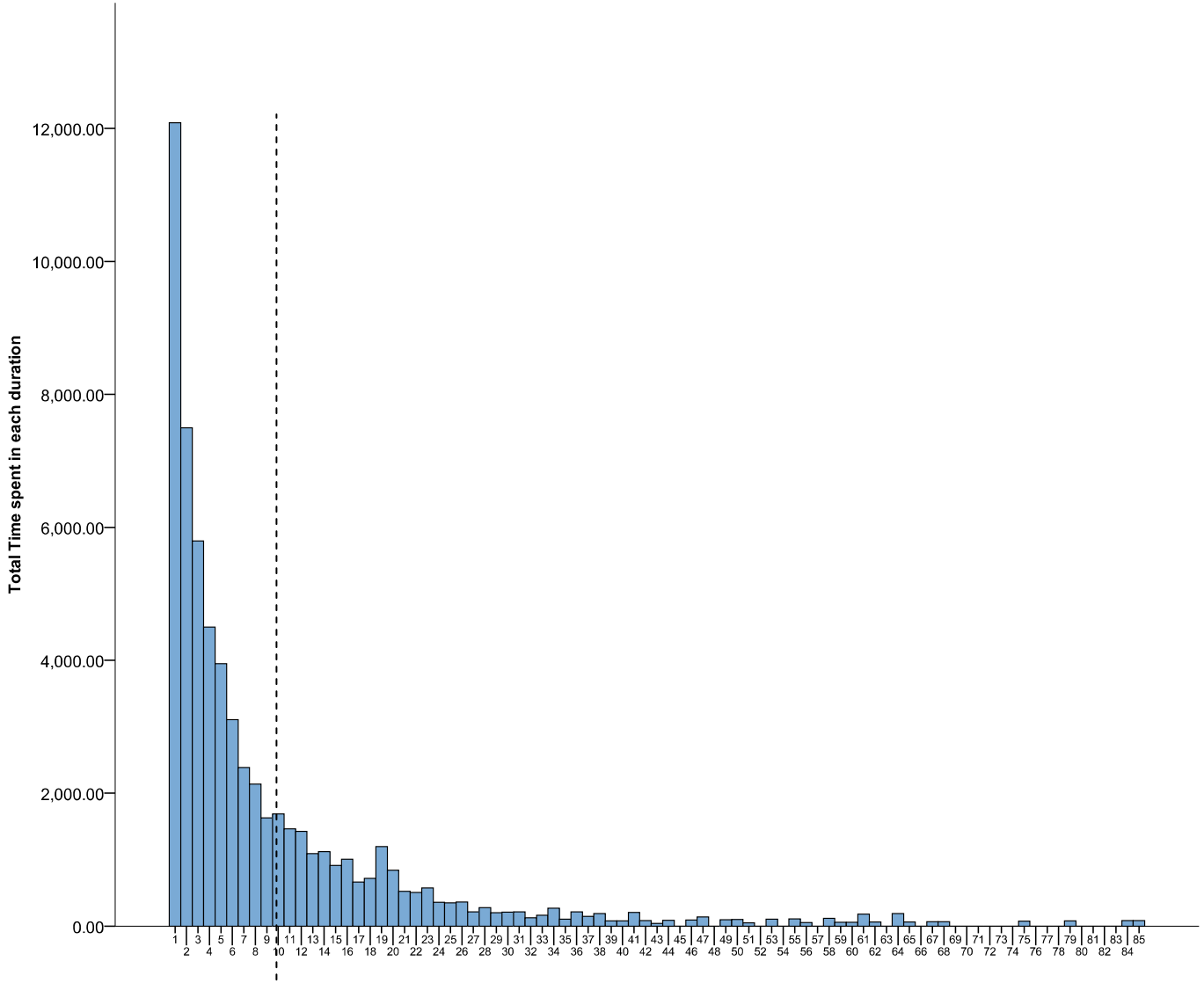
Figure 6.8 The physical activity level of the population defined by thresholds of activity



Does the label of 'active' depend on what measure of activity is used?

128 participants had available data for seven days and were eligible for the following analysis. For this analysis, a single bout of physical activity was considered any activity performed over 3 METs. There was such little activity that is considered 'vigorous' or 'very vigorous' (6-9 METs or above 9 METs respectively) that all activity over 3 METs was amalgamated. For all 128 participants, every bout of continuous physical activity was catalogued for duration and frequency over the seven-day period, ranging from one minute to 85 minutes. This was transformed into total time spent in bouts of various durations for the week. This was cumulated for the whole sample of 128, and data is displayed in figure 6.9. For example, we can see from this figure that for the whole group (n=128) over a seven-day period, approximately 12,000 minutes were spent in one-minute bouts of physical activity, 7,800 minutes spent in two-minute bouts of continuous physical activity, 5,900 minutes spent in three-minute bouts of continuous physical activity, etc. The dashed line on figure 6.9 represents the threshold of 10 minutes, which is recommended by the ACSM as the minimal duration of continuous physical activity that has a known clinical benefit when contributing towards a weekly target of >150 minutes of physical activity. This graph shows that most physical activity over 3 METs is accumulated in bouts of less than 10 minutes duration.

Figure 6.9 Cumulated total time spent in various bouts over 3 METs for the whole sample (n=128) during seven days



A Wilcoxon signed rank test was performed on total time spent over 3 METs during one week and time spent over 3 METs in bouts that were of at least 10 minutes duration. Results are displayed in figure 6.10. The dashed line in the figure represents the recommendation for physical activity of 150 minutes.

Table 6.5 shows the number and percentage of the sample which are labelled as 'active' according to physical activity guidelines by using 3 different measures; total time spent over 3 METs, time spent over 3 METs in at least 10 minute bouts and steps.

The relationship between steps and energy expenditure over 3 METs in at least 10 minute bouts is displayed in figure 6.11. The dashed lines demark the thresholds of the activity guidelines for each measure.

Table 6.5 Activity classification by three different variables

Active	150 minutes spent over 3 METs n (%)	150 minutes spent over 3 METs in ≥ 10 minute bouts n (%)	10,000 steps n (%)
Yes	103 (80.47)	32 (25)	15 (11.72)
No	25 (19.53)	96 (75)	113 (88.28)

Figure 6.10 Time spent above 3 METs in total and in bouts of at least 10 minutes

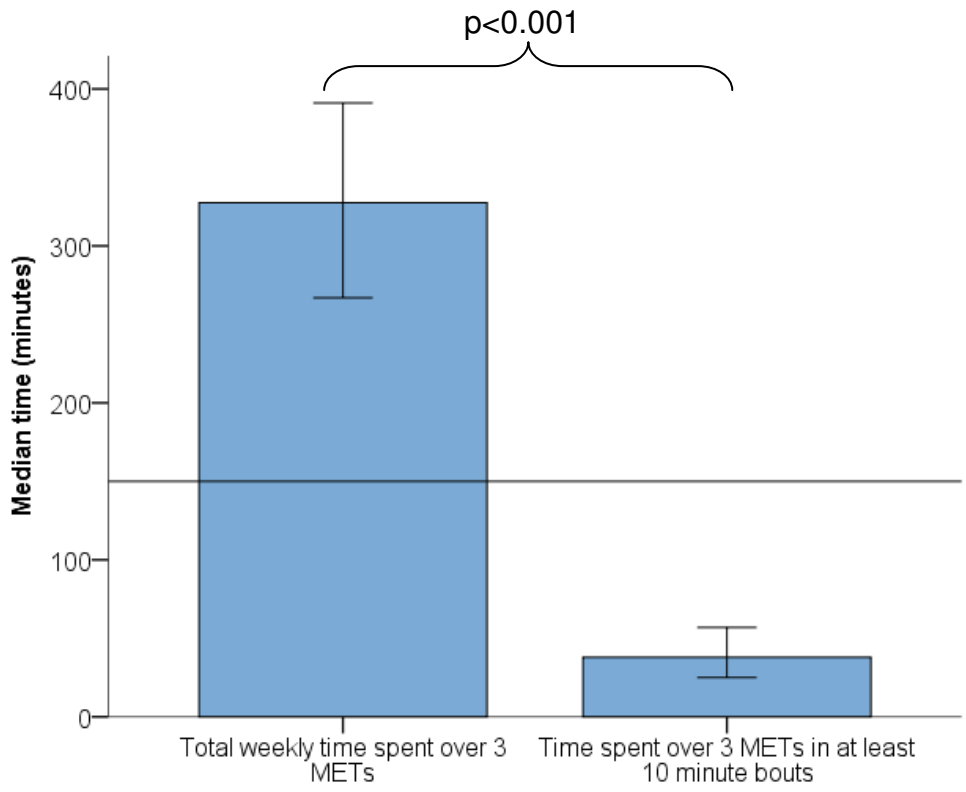
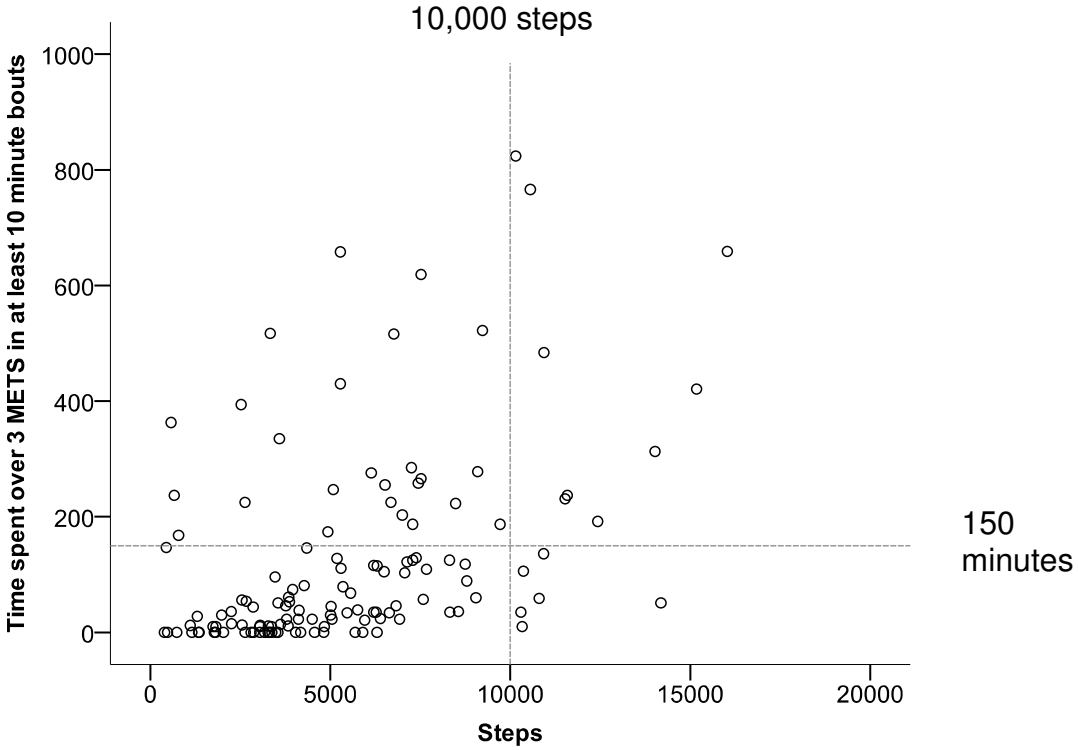


Figure 6.11 Scatter plot of steps and time spent over 3 METs in at least 10 minute bouts



6.5 Discussion

The aim of this chapter was to use the baseline activity monitor data from the trial described in chapter 3 to explore the activity levels of a sample of people with COPD who were managed in primary care. Using accelerometers, a range of measures were used from the SAB to describe the physical activity levels of the sample. Data were interrogated to establish if physical activity in this primary care population varied by disease or symptoms severity, as has been established in other research cohorts. Finally, the baseline physical activity monitor data of those who had worn the monitor for a whole week were evaluated to establish adherence to physical activity recommendations.

Physical activity in primary care

Physical activity of people with COPD managed in primary care has not previously been examined. The participants of this study had minimal contact with secondary care health services, despite relatively moderate lung function impairment (mean FEV_1 1.45 litres). It is not well understood why some patients manage in primary care while others require frequent use of secondary care services. While we might expect that increased utilisation of secondary care is required as the disease progresses, the moderately impaired lung function of these patients suggests that use of secondary care services is not solely associated with airflow obstruction. There may be a host of factors which influence an individual's ability to cope in primary care with their disease. This study provided the first opportunity to analyse a large sample of activity monitor data from people with COPD managed in primary care. It was anticipated that examination of their physical activity levels might

offer a unique perspective of the COPD patient, and may develop our understanding of why some patients seem to manage in primary care better than others. If activity levels in these patients were higher than in patients who engage with secondary care services, this could have generated a hypothesis that physical activity may be important associated with how patients cope with their COPD. This may have informed future research to test this hypothesis further.

Participants in this study had a mean step count of 5174 (SD 3129) and mean PAL of 1.76 (SD 0.78). This is marginally higher than findings from a study by Waschki et al. (2011) which recruited 170 patients, of a similar disease severity to the present study (mean FEV_1% predicted 58.8%), through a secondary care research database in Germany. The average step count of the sample was around 4,716 and the mean PAL 1.41. Troosters et al. (2010) recruited 70 people with COPD [mean (SD) FEV_1 1.48 (0.66) litres] from secondary care centres in Italy, Belgium and the USA. The total mean (SD) step count was 5584 (3360), which is slightly higher than in the present study. A small study of 17 participants post rehabilitation, in secondary care, with a mean FEV_1 of 1.1 litres had a mean step count of 5,646 (SD 3,471), which was slightly higher than that observed in the present study (Nguyen et al. 2011). It is possible, however, that activity levels were marginally higher because these patients had been recruited following rehabilitation which might have improved activity, although this was not confirmed by the study.

The findings of this chapter, within context of these three studies, suggest that despite being managed in primary care and appearing to cope well with their disease, the activity levels of the participants in the present study were similar to those observed in patients engaged in secondary care. Therefore, there is no indication to suggest that physical activity is associated with patients' ability to cope better in primary care. It should be noted, however, that the studies of patients managed in secondary care which have been described are all from non-UK centres. Referral into secondary care services may occur at different stages of the disease between different healthcare settings around the world, and therefore physical activity of patients managed in secondary care in other countries may be different to that of patients managed in secondary care in the UK. As yet there have been no direct comparisons made of physical activity in patients managed in primary and secondary care in the UK, and the question of whether any differences between these two populations exists remains.

Studies of healthy age matched controls have described average step counts of around 9,000 [n=30 (Troosters et al. 2010)], 10,000 [n=22 (Waschki et al. 2012)] to 11,000 [n=60 (Nguyen et al. 2011)] steps per day. Compared with the present study, this suggests that physical activity in people with COPD managed in primary care is low. However, the mean PAL of the healthy elderly described by Waschki et al. (2012) was lower than in the present study [mean (SD) 1.66 (0.19) vs. 1.76 (0.78) respectively], although this might be because the numbers of healthy controls was low (n=22) and may not be representative. Alternatively, this might reflect a difference between

ambulatory and non-ambulatory physical activity. Step count in the present study is reduced compared with studies of healthy controls, suggesting that ambulatory physical activity is impaired. However, the PAL, which incorporates any kind of physical activity, was slightly higher. This suggests the possibility that non-ambulatory activities may not be impaired in this sample, compared with healthy controls. This may be supported by work by Pitta et al. (2005b), which identified that patients spent a greater proportion of their time in lower intensity activities, such as sitting or lying, and less time in more moderate activities, such as standing or walking. Perhaps in people with COPD more attention to non-ambulatory activities should be paid in evaluation of physical activity in the future. To confirm this hypothesis future work could integrate physical activity monitoring alongside activity diaries to not only establish the intensity and duration of activity, but also the type of activity undertaken. This would be a novel area of research as the difference in ambulatory and non-ambulatory daily physical activity in people with COPD has not been explored.

Furthermore, the PAL was calculated by two different methods in the present study and that of Waschki et al. (2012). Waschki et al. used night-time energy expenditure from the SAB to estimate the basal metabolic rate, whereas the present study used the Harris-Benedict equation (Harris and Benedict 1918). There is no reason to suggest that either method is superior, however, this may be another reason why the PAL of the patients in the present study was similar to that of the healthy controls in the Waschki study.

Activity has previously been dissected by GOLD stage and MRC grade in a secondary care research population of patients with COPD (Watz et al. 2009). Watz and colleagues (2009) found that physical activity reduced with higher MRC scores and GOLD stage. This kind of analysis, however, has not been replicated in a primary care population before. Exercise capacity reduces between MRC grades 2 to 5 (Meijer et al. 2001; Spruit et al. 2007), therefore we might anticipate that the capacity for physical activity may also decline. Considering that with increased disease severity, in terms of airflow obstruction, activities of daily living require a greater proportion of one's aerobic capacity (Vaes et al. 2011) we might also assume that daily physical activity declines with higher GOLD stages. It is important to test these assumptions in order to understand how physical activity may change through the course of the disease, and therefore at what stage various interventions to target physical activity may be indicated.

The analyses in this chapter showed that while average step count varied between MRC grades, the PAL, energy expenditure and time over prescribed METs did not change between MRC dyspnoea grades 2 to 4. This suggests that daily physical activity might be broadly maintained between those who are MRC 2 to MRC 4. Physical activity, particularly in terms of the PAL and time over prescribed METs, declined sharply in those who were MRC grade 5. Watz et al. (2009) studied the physical activity of 170 patients recruited from a secondary care centre in Germany. Both step count and PAL demonstrated a gradual decline between MRC grades 2 and 5. The findings in the present study suggest that the decrease between MRC grades may not be as gradual,

particularly in the PAL. It is not immediately clear why the findings from these studies differ as the two samples were of a similar age and disease severity. It is possible that in the present study where patients were recruited from primary care, physical activity is better preserved in MRC grades 2 through 4 compared with patients managed in secondary care. Neither study, however, was adequately powered to detect differences between MRC grade, and therefore this may be natural variation. Additionally, the distribution of patients across the MRC grades may have different between the studies. While the Watz study does not report the number of patients in each MRC category, in the present study over half the sample were MRC grade 2 and only 10 were MRC 5. This is a more unusual distribution of patients than is usually seen in secondary care studies. This does highlights the need for more adequately powered research to understand how physical activity may change depending upon functional impairment.

There were significant differences in step count between GOLD stages II and III, and II and IV, and significant differences in the PAL between GOLD stages II and IV. Interestingly, however, is that those who were GOLD stage IV had a higher PAL than GOLD stage II [median (IQR) 2.05 (1.36 to 2.91) vs. 1.41 (1.15 to 2.12)]. This may be due to low numbers within each of the sub-groups, as this study was not adequately powered to detect this difference. It may also, however, highlight the difference between using a measure of functional impairment (like the MRC scale) compared with a measure of obstruction (like GOLD stage) to evaluate the impact of COPD on an individual's functional status. Evaluation of physical activity using the new

GOLD assessment of lung function or exacerbation history combined with health status measured by the CAT or MRC should be explored in the future.

Interestingly, these findings show that even those who are MRC grade 2 or GOLD stage I have reduced physical activity levels, compared with studies of healthy controls (Nguyen et al. 2011; Waschki et al. 2012). This is consistent with previous literature (Watz et al. 2009). This suggests that physical activity is modified early within the disease, if not prior to the onset of the disease (Hopkinson and Polkey 2010). The data reported in this chapter justifies the requirement for interventions aimed to improve physical activity early within the disease in patients managed in primary care.

Adherence to physical activity recommendations

Physical activity guidelines have proposed that older adults should carry out around 150 minutes of moderates intensity (>3 METs) activity per week (Nelson et al. 2007), or around 10,000 steps per day (Le Masurier et al. 2003). Historically, physical activity has been measured as self-report, however more recently the development of objective devices such as pedometers and accelerometers has initiated a wealth of studies which have measured activity by these means. While the use of these devices addresses the issue of subjective bias from self-report data, there are still difficulties with handling and interpreting the data they produce.

The SAB produces several measures from its basic output, including TEE, steps, and time/ energy expenditure over a defined threshold. From this

output it is possible to derive other variables, such as the PAL. The advanced function of the monitor allows further interrogation of a minute-by-minute account of energy expenditure which allows for calculation of the duration of bouts of physical activity. The data presented in this chapter, particularly that shown in figure 6.10 and in table 6.5 demonstrates the disparity between the different measures. Depending on the measure used, anything between 11% and 80% of the sample may be described as meeting the guidelines for physical activity. In reporting the prevalence of inactivity in a given population, this highlights the importance of selecting appropriate measures produced by these devices.

Some studies have reported total time spent above 3 METs, although have not reported time spent over 3 METs in at least 10 minute bouts (Troosters et al. 2010; Watz et al. 2009). The recommendations for physical activity state that 150 minutes of moderate activity per week should be accumulated through bouts of at least 10 minutes. The findings from this chapter show there is a significant difference between the total activity over 3 METs and activity over 3 METs accumulated through at least 10 minute bouts [median (IQR) 327 (167.75-573.50) minutes vs. 38 10.00-121.25) minutes]. The health benefits of bouts of activity less than 10 minutes are unclear, and do not fulfil the criteria of the current guidelines (Nelson et al. 2007). To avoid overestimation of adherence to physical activity guidance it would be recommended that time spent over 3 METs in at least 10 minute bouts should be reported. For some patients, however, bouts of 10 minutes at moderate intensity might not ever be achievable, even through regular physical training.

If measuring activity at several time-points, in order to ensure changes in physical activity are not missed in these patients, total time spent over 3 METs should still be reported.

Step count is another variable that can be used to report on adherence to physical activity guidelines, with a target of 10,000 steps per day. Figure 6.11 shows that although there is a relationship between moderate activity and steps, there is not always agreement between the two measures as to which patients meet physical activity guidelines. All scatter points within the top right hand quarter of the graph represent patients who meet physical activity criteria by both methods of assessment, where as those in the top left and bottom right quarters represent patients who met one criteria but not the other. This disagreement suggests the need for using more than one variable to describe physical activity levels. If just one of these measures is selected then we may underestimate the proportion of patients that meet physical activity recommendations.

The only other study which has assessed bouts of activity was published recently (Donaire-Gonzalez et al. 2012). It was a Spanish study which recruited patients from a tertiary hospital. This study used two difference thresholds for moderate physical activity. A value of 2.6 METs was derived as 50% of maximal oxygen uptake on performing an incremental test. The second value used was the traditional application of 3 METs to denote moderate intensity activity. When using 2.6 METs, 61% of the sample (n=177) were considered to meet the guidelines, whereas using 3 METs, 50% of the

sample met the guidelines. This is considerably higher than the 25% of the sample in this study which met the criteria of ≥150 minutes of moderate activity per week in at least 10 minute bouts.

It is not clear why the difference in these findings exists. A similar methodological approach was applied to both studies, and both used the SAB. The groups were similarly matched for age and FEV_1, although the physical function of the Spanish cohort was quite high, with a mean (SD) 6MWD of 407 (96) m. It may be that physical activity is highly variable across different cultures, climates, socio-economic backgrounds and between different hospital settings (Meijer et al. 2001; Pitta et al. 2009), and has also shown seasonal variation (Sewell et al. 2010). There is also likely to be natural variation in physical activity that could account for some of the difference between studies.

Other non-COPD studies of adult populations have found that around 28-48% of the general adult population meets the ACSM criteria for physical activity (Martin et al. 2000; Meseguer et al. 2009 ; Rydwik et al. 2012). Given these estimates in the general healthy population, the findings by Donaire-Gonzalez et al. (2012) that suggest 50-60% of those with COPD meet the ACSM criteria seems high. This highlights that physical inactivity is not a problem restricted to COPD, but is a wider public health concern.

Limitations

This was a cross-sectional observation of physical activity during a single snapshot during a seven-day period. This study has evaluated people at different stages of the disease process and attempted to interpret this to predict how physical activity may progress. Repeated measures of activity over a long follow-up are required to develop our understanding of how physical activity actually changes through the life span of individuals with COPD. There is presently a lack of literature which measures physical activity longitudinally, most likely because this kind of research is challenging to conduct.

Another limitation of this study is that only one measure of physical activity, the SAB, was used. While the SAB is a well validated device for objectively capturing physical movement, it offers no insight into the actual purpose of the activity. For example, it is possible to see that movement has occurred, but we cannot tell whether that was for getting dressed, going for a walk, doing the shopping, etc. Some monitors, such as the Dynaport, are able to record time in different positions, such as lying, sitting, standing or walking, which may offer greater insight into the type of activity conducted. Additionally, the conjunction of accelerometry and physical activity diaries might provide more understanding of why activity is undertaken, e.g. for leisure, work or ADLs.

Areas for future research

Thus far, only this and the Spanish study have evaluated bouts of activity in line with recommendations. Differences between these countries exist in

terms of culture, climate, terrain, and the healthcare systems. It is likely be valuable to explore this further in other cultures also, as this may have a significant bearing on the findings.

It is likely that there are a number of people with COPD who will never be able to achieve bouts of 10 minutes of moderate activity. There may still be value in performing physical activity in bouts of less than 10 minutes as this may be a measure of exercise, however at present this has not been verified. The value of activity in shorter bouts should be explored further in order to adequately prescribe recommendations for those who operate at a lower threshold.

Finally, this study has demonstrated the importance of making the distinction of measuring moderate physical in bouts of 10 minutes. It is not yet known whether this measure can be improved following an intervention aimed to improve physical activity. This is explored in chapter 7 of this thesis, however should also be addressed in other fields, such as pulmonary rehabilitation.

Conclusions

The measurement of physical activity is complex. Even with the advent of sophisticated accelerometers, issues around reporting of variables exist. It is apparent from the body of literature, that although there may be large variability in physical activity data, physical activity in patients with COPD is low. This study of patients managed in primary care aimed to explore the physical activity levels of a sample of patients who are relatively low users of

healthcare, compared with much of the literature so far which have documented physical activity in patients in secondary care who are more likely to be high users of healthcare. The findings in this chapter suggest that physical activity of the patients in this study are similar to other samples of patients recruited from secondary and tertiary health services in other studies, and lower than studies of healthy controls. Even patients who might be considered mild, in terms of MRC grade or GOLD stage, have low levels of activity. These findings highlight the need for interventions to improve physical activity in all patients with COPD in primary care, regardless of their level of functional disability or airflow limitation.

So far, studies have used accelerometers to report time spent in moderate physical activity. The ACSM guidelines recommend that 150 minutes per week of activity over 3 METs is required for a healthy lifestyle, however this activity should be accumulated in bouts of at least 10 minutes. The data presented in this chapter shows a significant difference between total activity over 3 METs and activity over 3 METs accumulated in at least 10 minute bouts. This has important implications for how these data are interpreted and the clinical meaningfulness of the measure. More than half of total activity over 3 METs was accumulated in less than 10 minute bouts, the clinical relevance of which is not known. In the future, research measuring moderate physical activity through accelerometry should report duration accumulated through at least 10 minute bouts, and studies aiming to promote a healthier physically active lifestyle should use this as an outcome.

Chapter 7 Physical activity following SPACE FOR COPD: does it change and can it be predicted?

7.1 Introduction

In chapter 6 of this thesis, methodological and practical difficulties around activity monitoring were considered. A number of approaches were used to analyse and describe baseline accelerometer data from all participants of the trial. In meeting the ACSM guidelines for physical activity, the average amount of activity conducted in the group was low. Only 25% of the current population met the minimum criteria of 150 minutes of moderate activity accumulated in bouts of at least 10 minutes, and only 12% met the recommended 10,000 steps per day.

Physical activity is a health behaviour which has important clinical implications for people with COPD, and has been associated with several poor long-term outcomes (Garcia-Aymerich et al. 2003; Garcia-Aymerich et al. 2006; Waschki et al. 2011). Self-management aims to promote positive changes in health behaviour, and SPACE FOR COPD has placed a particular emphasis on improving physical activity and exercise performance. As discussed in the previous chapter, it is challenging to predict how physical activity may change. This chapter will therefore use a range of measures produced by the SenseWear Armband from data collected over the study period to explore the impact of SPACE FOR COPD on physical activity. This will then be discussed within the context of other study findings.

7.2 Aims

The aims of this chapter are:

i) to evaluate the impact of SPACE FOR COPD on physical activity

ii) to establish which, if any, characteristics can predict physical activity

7.3 Methods

The main trial design is described in more detail in chapter 3. Section 6.2 in chapter 6 describes in detail how the different variables, which will also be used in this chapter, were derived from the SenseWear Armband.

Participants

All participants in the study were eligible for inclusion in this analysis. If participants did not attend follow up, or did not wear the activity monitor for any of their three visits then these participants were excluded.

As in the previous chapter, days were excluded if the monitor was worn for less than 12 hours. Participants were also excluded from analysis if there were less than three days available at each time point.

Outcome measures

Participants were asked to wear the SenseWear Pro3 ArmBand (SAB) for seven whole days following their baseline, six-week and six-month assessments. The monitor automatically provides several measures, such as total energy expenditure and steps. It is also possible to derive further

variables by using the professional advanced software. The variables which were derived from the monitor and used in this analysis were:

- Total energy expenditure (TEE), expressed as Kilocalories (Kcals)
- Steps
- Energy expenditure over prescribed METs
- Time over prescribed METs
- Time over 3 METs in at least 10 minute bouts
- Physical Activity Level (PAL)

In order to standardise outcome measures over three time points only the first 12 hours of each day's data were recorded. This controlled for time in the calculation of any change in the amount of activity undertaken, and this 12-hour period has been used by several other studies in the evaluation of physical activity (Breyer et al. 2010; Pitta et al. 2008).

Analysis

Data was checked for normality and outliers. Baseline differences between those included and those not included in the activity monitor study were examined with independent t-tests for parametric data and chi square for non-parametric data. Of those included in this analysis, baseline differences between intervention and control were calculated using the same tests. Between-group differences from baseline to six weeks were tested for with independent t-tests. Between-group differences over time at six months were tested for by repeated measures analysis of variance (ANOVA). The number of participants achieving more than 150 minutes over 3 METs at each time

point were calculated using SAS and compared by using a Kruskal-Wallis test. Linear regression analyses were performed in the attempt to produce a model which could predict those more likely to increase their physical activity levels. All analyses were carried out on PASW version 18.

7.4 Results

The baseline differences between those included and not included in this aspect of the study are reported in table 7.1. Tables 7.2 and 7.3 present the baseline data of SPACE FOR COPD and usual care groups of those included in the study. Data was missing for 15 participants because there was an error upon downloading activity monitor data. 35 sets of data were missing due to withdrawal from the trial, 25 participants had not worn the monitor for long enough at one of their time points and there was a further 26 participants who had missing data because they had not worn the monitor.

Table 7.1 Baseline characteristics of those included and not included in activity monitor analysis

		Included (n=83)	Not included (n=101)	p value
Male: Female [n (%)]		43 (51.80) : 40 (48.20)	58 (57.43) :43 (42.57)	0.446
Age (years) [mean (SD)]		69.2 (9.4)	69.8 (9.0)	0.916
FEV_1 (litres) [mean (SD)]		1.44 (0.55)	1.46 (0.57)	0.833
BMI [mean (SD)]		26.85 (4.81)	28.21 (5.59)	0.080
CRQ-SR [mean (SD)]	**Dyspnoea**	3.16 (1.12)	3.08 (1.25)	0.636
	Fatigue	3.99 (1.18)	3.88 (1.28)	0.550
	Emotion	5.00 (1.11)	4.80 (1.32)	0.272
	Mastery	5.33 (1.29)	5.13 (1.40)	0.325
ISWT (m) [mean (SD)]		346.4 (132.7)	327.6 (175.7)	0.073
ESWT (seconds) [mean (SD)]		257.2 (170.3)	273.2 (191.6)	0.768
HADS [mean (SD)]	**Anxiety**	5.91 (3.68)	6.81 (4.33)	0.136
	Depression	4.69 (2.97)	5.67 (3.39)	0.042
Bristol Knowledge COPD Questionnaire [mean (SD)]		34.85 (8.74)	32.56 (8.33)	0.108
MRC [n (%)]				
2		45 (54.22)	53 (52.48)	0.624
3		23 (27.71)	23 (22.77)	
4		11 (13.25)	16 (15.84)	
5		4 (4.82)	9 (8.91)	
Lives with [n (%)]				
Spouse		51 (61.44)	61 (60.40)	0.614
Alone		20 (24.10)	20 (19.80)	
Family		6 (7.23)	13 (12.87)	
Other		6 (7.23)	7 (6.93)	

Table 7.2 Baseline characteristics of SPACE FOR COPD and usual care groups included in activity monitor analysis

		SPACE (n=39)	Usual care (n=44)	p value
Male: Female [n (%)]		24 (61.54): 15 (38.46)	19 (43.18):25 (56.82)	0.095
Age (years) [mean (SD)]		67.5 (7.5)	70.6 (10.7)	0.136
FEV_1 (litres) [mean (SD)]		1.45 (0.62)	1.48 (0.47)	0.767
BMI [mean (SD)]		27.60 (5.56)	26.69 (4.38)	0.405
CRQ-SR [mean (SD)]	**Dyspnoea**	3.31 (1.03)	3.00 (1.11)	0.973
	Fatigue	4.06 (1.30)	3.84 (1.08)	0.189
	Emotion	5.00 (1.30)	4.97 (0.99)	0.918
	Mastery	5.38 (1.38)	5.32 (1.26)	0.819
ISWT (m) [mean (SD)]		346.9 (126.4)	345.9 (139.4)	0.973
ESWT (seconds)		244.6 (174.0)	268.2 (168.2)	0.531
HADS [mean (SD)]	**Anxiety**	5.72 (4.02)	6.91 (3.59)	0.158
	Depression	4.90 (3.51)	5.89 (2.44)	0.987
Bristol Knowledge COPD Questionnaire [mean (SD)]		36.55 (7.32)	34.61 (10.23)	0.368
MRC [n (%)]				
2		19 (48.72)	26 (59.09)	0.735
3		13 (33.33)	10 (22.73)	
4		5 (12.82)	6 (13.64)	
5		2 (5.13)	2 (4.55)	
Lives with [n (%)]				0.787
Spouse		23 (58.97)	28 (63.64)	
Alone		11 (28.21)	9 (20.45)	
Family		3 (7.69)	3 (6.82)	
Other		2 (5.13)	4 (9.09)	

Table 7.3 Baseline activity monitor data of SPACE FOR COPD and usual care groups

	SPACE FOR COPD (n=39)	Usual care (n=44)	p value
Total Daily Energy Expenditure (Kcals) [mean (SD)]	1386.2 (378.7)	1324.9 (302.6)	0.249
Energy Expenditure over prescribed METs (Kcals) [median (IQR)]	81.4 (45.1 to 187.9)	61.0 (13.4 to 132.1)	0.383
Time over prescribed METs (minutes) [median (IQR)]	13.4 (7.4 to 34.5)	10.1 (2.6 to 24.8)	0.336
Steps (number) [mean (SD)]	5062.7 (3043.0)	5337.2 (2801.7)	0.962
Time over 3 METs in ≥ 10 minute bouts (minutes) [median (IQR)]	45.00 (10.00-155.00)	38.00 (12.00-99.00)	0.321
Physical Activity Level [mean (SD)]	1.73 (0.63)	1.73 (0.94)	0.971

The median (IQR) number of days the activity monitor was worn for was 7 (7-7) at baseline, 7(7-7) at six weeks and 7(7-7) at six months. The output of the six activity monitor variables at all three time points are described in table 7.4. Results from the independent t-tests showed that there was a significant between-group difference in change in steps at six weeks (p=0.047). All other between-group differences were not statistically significant. The results of the repeated measures ANOVA are displayed in table 7.5. Change in time over 3 METs in at least 10 minutes bouts, physical activity level and steps are illustrated in figures 7.1-7.3.

Table 7.4 Activity monitor output at three time points for SPACE FOR COPD and usual care groups

		Baseline	6 weeks	6 months
Total Daily Energy Expenditure (Kcals)	**SPACE mean (SD)**	1386.2 (378.7)	1405.7 (3131.8)	1454.74 (415.43)
	Usual care mean (SD)	1324.9 (302.6)	1312.68 (338.48)	1305.94 (415.43)
	Between-group difference (95%CI)	61.3 (-87.7 to 210.2)	93.06 (-55.0 to 241.1)	148.8 (-24.1 to 321.7)
Energy Expenditure over prescribed METs (Kcals)	**SPACE median (IQR)**	81.4 (45.1 to 187.9)	94.50(38.60-218.00)	96.00(29.33-169.00)
	Usual care median (IQR)	61.0 (13.4 to 132.1)	92.75(13.68-195.54)	75.00(13.17-216.88)
	Between-group difference (95%CI)	20.4 (-38.1 to 101.4)	1.75 (-43.5 to 75.7)	21.00 (-73.1 to 43.2)
Time over prescribed METs (minutes)	**SPACE median (IQR)**	13.4 (7.4 to 34.5)	17.00(7.60-37.17)	16.83(5.00-29.50)
	Usual care median (IQR)	10.1 (2.6 to 24.8)	13.85(2.80-24.70)	13.53(1.58-38.75)
	Between-group difference (95%CI)	3.3 (-11.3 to 85.2)	3.15 (-13.5 to 13.2)	3.30 (-19.4 to 6.0)
Steps (number)	**SPACE mean (SD)**	5062.7 (3043.0)	5450 (3132)	5260 (3220)
	Usual care mean (SD)	5337.2 (2801.7)	5132 (3052)	5147 (2918)
	Between-group difference (95%CI)	-275 (-1551.1 to 1002.1)	318 (-1107.0 to 1743.2)	113 (-1299.1 to 1536.7)
Time over 3 METs in ≥ 10 minute bouts (minutes)	**SPACE median (IQR)**	45.00(10.00-155.00)	96.00(28.00-246.00)	51.00(11.00-143.00)
	Usual care median (IQR)	38.00(12.00-99.00)	39.00(3.00-135.300)	49.00(8.00-117.00)
	Between-group difference (95%CI)	7.00 (-63.0 to 59.2)	57.00 (-10.9 to 123.3)	2.00 (-59.5 to 72.4)
Physical Activity Level	**SPACE mean (SD)**	1.73 (0.63)	1.78 (0.63)	1.81 (0.59)
	Usual care mean (SD)	1.73 (0.94)	1.77 (0.96)	1.75 (0.93)
	Between-group difference (95%CI)	0.0 (-30.36 to 0.34)	0.01 (-0.67 to 0.39)	0.06 (-0.31 to 0.42)

Table 7.5 Significance levels of within-subject effects of time and intervention and between-subject effects for activity monitor output

	Within-subject effects		Between-subject effects (p value)
	Time (p value)	Time*Intervention (p value)	
Total Daily Energy Expenditure (Kcals)	0.757	0.729	0.102
Energy Expenditure over prescribed METs (Kcals)	0.609	0.333	0.827
Time over prescribed METs (minutes)	0.691	0.304	0.802
Steps (number)	0.670	0.609	0.898
Time over 3 METs in ≥ 10 minute bouts (minutes)	0.137	0.191	0.418
Physical Activity Level	0.455	0.600	0.603

This indicates that there were no effects of either time or intervention on physical activity. There were therefore no between-group differences in any of the physical activity measures over the six months.

Figure 7.1 Time spent over 3 METs in at least 10 minute bouts at all time points for both SPACE FOR COPD and usual care groups

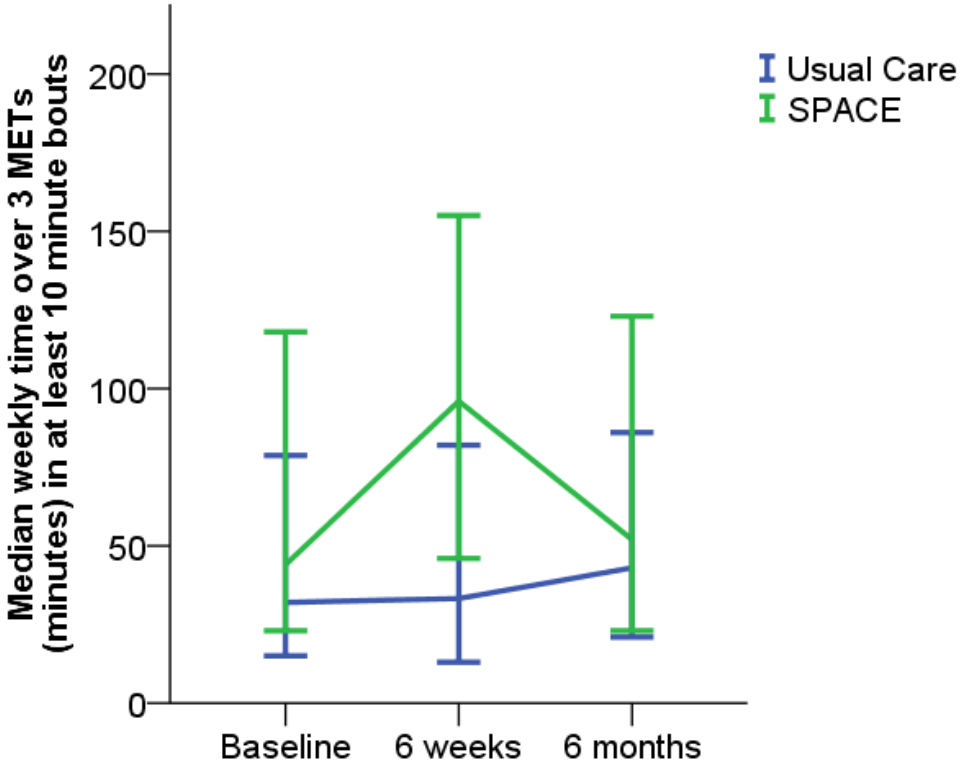


Figure 7.2 Physical Activity Level at three time points for both SPACE FOR COPD and usual care groups

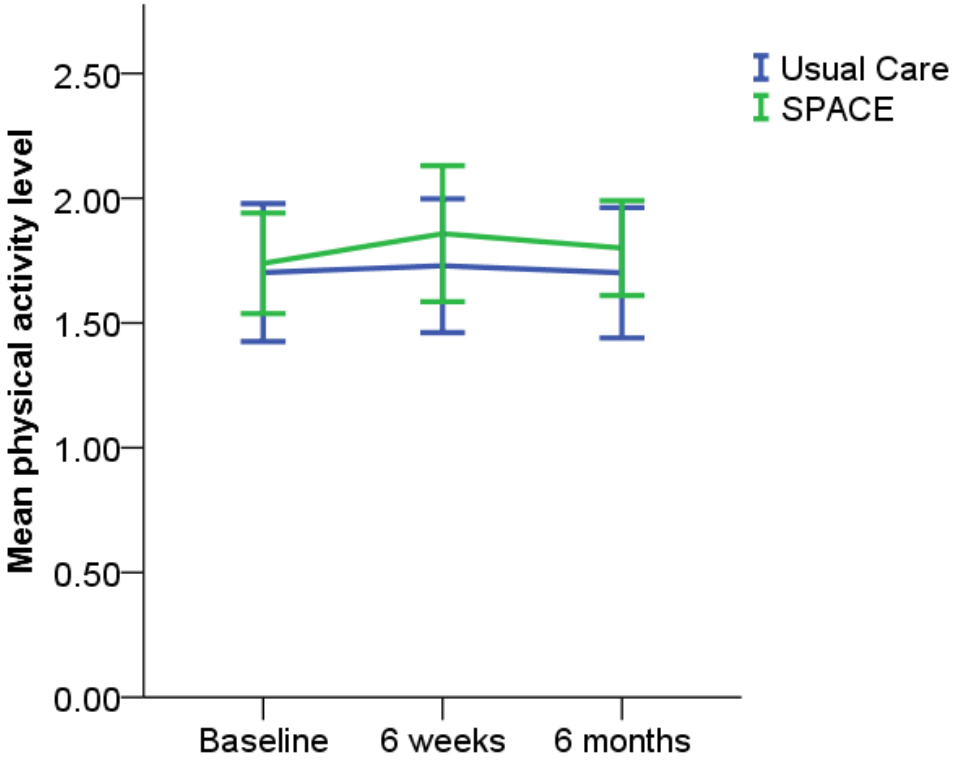
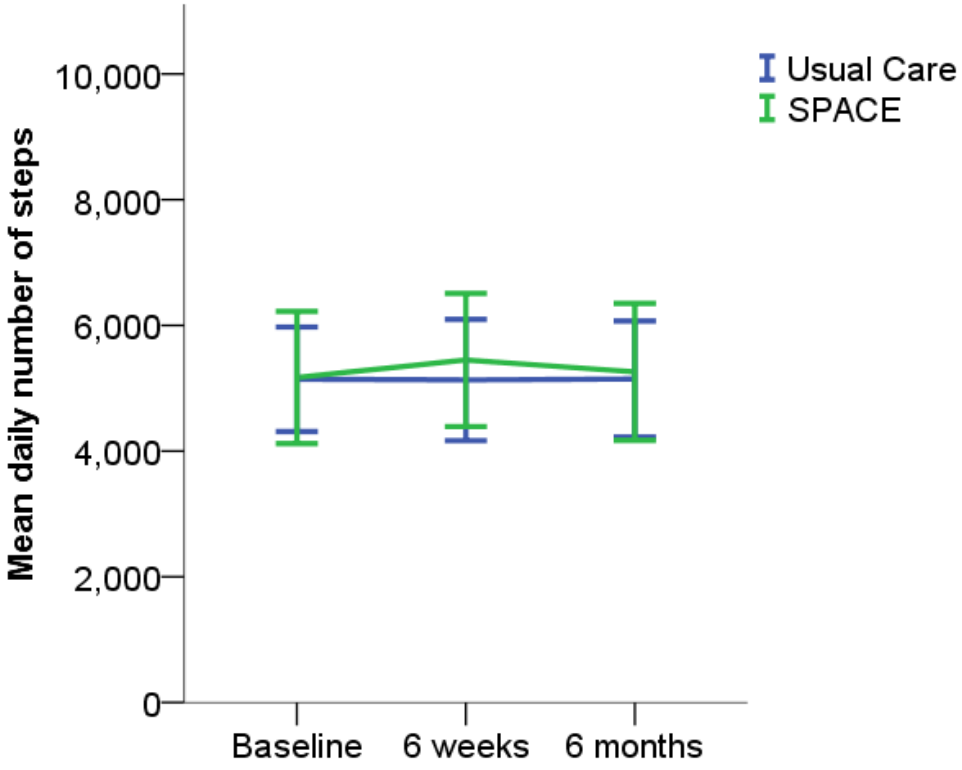


Figure 7.3 Number of steps at all time points for both SPACE FOR COPD and usual care groups



Number of patients achieving physical activity guidelines

In order to evaluate the number of people achieving the ACSM guidelines only those who had seven full days of data at all three time points were included in this analysis. There were 55 participants who fulfilled this criteria, n=29 in usual care and n=26 in the SPACE FOR COPD group. Table 7.6 describes the number of participants at each time point in each group who were compliant with the ACSM guidelines of at least 150 minutes of activity over 3 METs in bouts of at least 10 minutes. The results of the Kruskal-Wallis test are also shown in this table.

Table 7.6 Participants compliance with ACSM guidelines at three time points

		Baseline	6 weeks	6 months
Achieving ≥150 minutes over 3 METs in ≥10 minute bouts	**SPACE yes: no [n (%)]**	4(15.40): 22(84.60)	8(30.80): 18(69.20)	4(15.40): 22(84.60)
	Usual care yes: no [n (%)]	7(24.10): 22(75.90)	7(24.10): 22(75.90)	5(17.20): 24(82.8)
	Between-group significance (p value)	0.422	0.585	0.854

Overall there was no statistically significant between-group difference in the numbers of patients who achieved the recommendations for physical activity over the six months. There was, however, a non-significant increase of 15% more patients achieving the guidelines at six weeks.

Predicting change in physical activity

Although not statistically significant, figure 7.1 suggests there may a trend for increased time spent over 3 METs in ≥ 10 minute bouts in the SPACE FOR COPD group at six weeks. In order to predict who might be most likely to improve in this outcome at six weeks, linear regression analysis was performed. Baseline characteristics of; age, FEV_1, FVC, BMI, gender, baseline ISWT distance, baseline ESWT distance, baseline BCKQ, baseline PRAISE, change ISWT, change ESWT, change BCKQ and change PRAISE were used in a backward stepwise linear regression model to predict change in time spent over 3 METs in ≥ 10 minute bouts in the SPACE FOR COPD group from baseline to six weeks. The only significant predictor was baseline

MRC grade which was able to predict 10% of the variability in change in time spent in activity over 3 METs in ≥ 10 minute bouts in the SPACE FOR COPD group at six weeks.

7.3 Discussion

These data suggest that there is some improvement in physical activity at six weeks in the SPACE FOR COPD group, however this is not maintained at six months. It was not, however, possible to predict who was most likely to increase physical activity with the variables that had been collected.

Given the high variation in most measures of activity, achieving adequate power to detect a difference is likely to require large numbers of patients. This study was not adequately powered to detect a change in activity levels. The examination of these data, therefore, was for exploratory purposes to signal where and what changes might occur. This may assist us in generating hypotheses, which could be tested in future work.

Meeting physical activity guidelines

The guidelines for physical activity recommend that at least 150 minutes per week should be spent in moderate intensity activities which should be accumulated in bouts of at least 10 minutes duration (Haskell et al. 2007). At baseline, the median length of time in both groups did not meet this requirement at 45 and 38 minutes for SPACE FOR COPD and usual care respectively. After six weeks however there was a change of 51 minutes in the SPACE FOR COPD group and only a 1 minute change in usual care. This

means that for those on SPACE FOR COPD, on average, activity that contributed towards meeting the ACSM guideline was more than doubled during the first six weeks. While the lack of statistical significance suggests this could have occurred by chance, the size of this change suggests it may still be worth considering the implications.

This is the first study of a COPD primary care population to scrutinize physical activity in this way. The effect of an intervention on adherence to physical activity guidelines has not previously been described. While as yet there are no studies which show a cause and effect that improving the physical activity levels of people with COPD will lead to improved survival, the widening body of literature suggests there is an association between the two (Garcia-Aymerich et al. 2006; Waschki et al. 2011). We therefore make an assumption that improving activity is beneficial, and that meeting the guidelines should be the overall aim.

There was not a significant change in the number of people who met the criteria of 150 minutes over 3 METs in at least 10 minute bouts overall. However, given that the average baseline time was only around one quarter of the recommended amount, most patients were far from achieving the 150 minutes. Perhaps for many people with COPD, 150 minutes over 3 METs in 10 minute bouts is more challenging than for most, or perhaps an unrealistic target altogether. Using time as a continuous variable rather than dichotomising below and above 150 minutes may therefore be a more useful measure in this population.

Only one other self-management study has previously attempted to report changes in physical activity in patients with COPD. COPE II (Effing et al. 2011) used a Yamax digiwalker 200 pedometer to count steps, which patients wore for seven days at baseline, seven months and 12 months. Over the treatment period (12 months) there was a net improvement of 1,190 steps per day, which was approximately an 18% improvement on baseline activity and was statistically significant (p=0.028). This change was only weak-moderately correlated with change in ISWT (r=0.47) and ESWT [r=0.38) (Zwerink et al. 2012)]. These data suggest that physical activity and exercise performance are not well associated, and supports the discussion in the previous chapter, which suggested that what one can do and what one does may be quite different.

A key difference between COPE II and SPACE FOR COPD is the intensity and duration of the interventions. COPE II required patients to attend supervised exercise two to three times per week for up to one year, whereas SPACE FOR COPD was an entirely unsupervised programme which only provided planned support for the first four weeks. Perhaps the sustained support in COPE II was important for maintaining longer-term behaviour change. The short-term support in SPACE FOR COPD may explain why physical activity appears to show signs of improvement during the first six weeks, but returns to baseline after the withdrawal of formal support by six months. The point is worthy of consideration in planning for future research studies and implementation of SPACE FOR COPD in a clinical context.

Although the improvement in steps in COPE II was significant, there are drawbacks with the design. Pedometers have been found to be less reliable than accelerometers at detecting slow speeds on walking (Turner et al. 2012), therefore not all walking may have been captured by the device. Additionally, step count alone is a rather crude insight into physical activity. It gives no information about either intensity or duration of activity. It is not possible, therefore, from the COPE II study to establish the level of adherence of the population to the ACSM guidelines. The data from the SPACE FOR COPD trial offers a more meaningful insight into using a range of physical activity parameters.

Predicting change in physical activity

This is the first study which has attempted to establish whether any other variables can predict change in activity. A linear regression model was used to evaluate whether any of the characteristics of this population could predict the change in moderate activity performed in bouts between baseline and six weeks. Of all the variables entered into the model, only baseline MRC score was found to be a significant predictor, which was able to predict around 10% of the variance of the change in time spent over 3 METs. This suggests that with the variables collected in this study, it is not possible to predict change in physical activity.

It is interesting that neither baseline nor change in either knowledge or self-efficacy were significant predictors of change in physical activity behaviour. It has been previously postulated that a self-management intervention which

enhances knowledge, skills and self-efficacy results in behaviour change and impacts on healthcare utilisation and health status [Figure 7.4 (Bourbeau, Nault, and Dang-Tan 2004)]. While the author acknowledges this is a simple model, the data and analysis in this chapter does not support this theory.

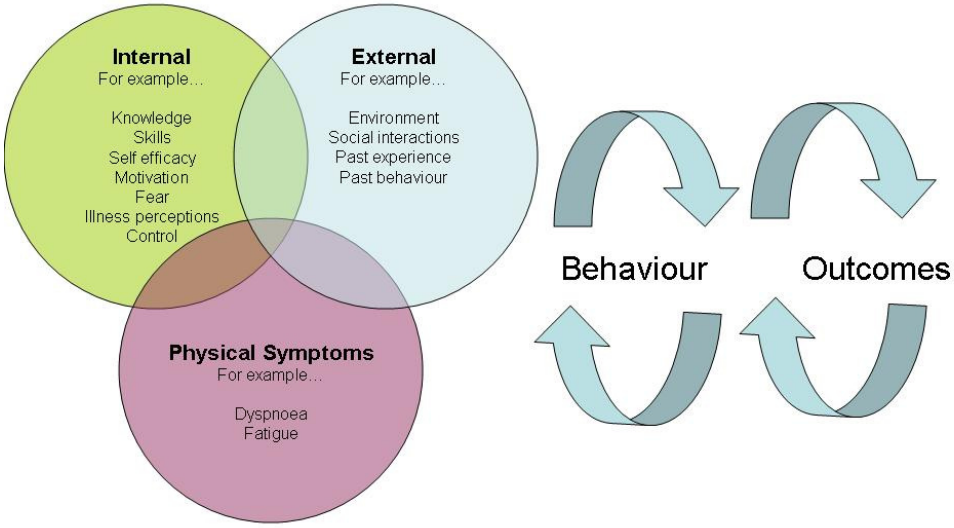
Figure 7.4 Bourbeau's model of behaviour change (Bourbeau, Nault and

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

measure self-efficacy, knowledge and behaviour change were not appropriate, and using different measures may have produced an alternative result. All the measures used however (BCKQ for knowledge, PRAISE for self-efficacy and the SAB for physical activity) have been validated in COPD populations. While the BCKQ and PRAISE were originally designed for pulmonary rehabilitation populations, there is a lack of choice of other tools validated in people with COPD. It is also worth noting that this is the first self-management study to measure knowledge, self-efficacy and behaviour

change to test any relationship between the three constructs, and is the first time the theory proposed in figure 7.4 has been tested by objective measures. As recognised by the author himself (Bourbeau, Nault, & Dang-Tan 2004), it is likely that this model is an overly simplistic concept of behaviour change. Previously it was discussed that just because people have greater exercise capacity, it does not necessarily translate into physical activity behaviour change. There are parallels here insofar that having the knowledge and self-efficacy to do more, also does not necessarily mean that people actually will do more. Figure 7.5 is modelled on the work by Bourbeau, Nault and Dang-Tan (2004), but illustrates that there is likely to be a host of internal factors, external factors as well as symptoms, which contribute to the complexity of people's choice around undertaking physical activity. It is possible that some of these factors may be influenced by programmes such as self-management; however others may be very difficult to manipulate. Behaviour change, in terms of physical activity, remains therefore a very unclear area of our understanding in people with COPD.

Figure 7.5 Model of behaviour change



Limitations

There are still no clear guidelines on measuring physical activity, and methodologies in the current literature are varied. Several methodological decisions were made which will have had implications for the findings of this chapter. The decision to only include the first 12 waking hours of data from each participant was taken to ensure standardisation, so that comparisons could be made in the knowledge that a like for like time-frame was used at each time-point. This does, however, come at the expense of not using data where the monitor was worn for longer than 12 hours. This study may therefore have underestimated physical activity levels in some participants, and this is accepted as a drawback of this methodology. By using the first 12 waking hours, however, it was anticipated that this would capture the majority of patients' 'most active' time of day. It was decided to use 12 hours on the

basis of previous studies which have assessed physical activity (Breyer et al. 2010; Pitta et al. 2009; Pitta et al. 2008). However, data may still be a valid reflection of activity for periods of less than 12 hours (Hill et al. 2012). This would have been excluded in this study. At present we do not know the minimum number of hours required in order to be accurately representative of an individual's daily activity levels. This is an area for further research in order to inform future studies.

A further issue with the measurement and reporting of physical activity in this study is that with accelerometry alone, it is not possible to understand neither the nature nor purpose of the movement that the monitor has detected. This chapter has moved the literature forward by analysing adherence to physical activity guidelines for the first time by looking at both intensity and duration of activity. However, it is still not possible to tell how this activity was accumulated, for example cycling or walking. Physical activity questionnaires or diaries, although criticised for being prone to subject bias, are able to provide more detail regarding the purpose of activity. A combination of both questionnaires and accelerometry perhaps provide the best overall picture of the actual amount, nature and purpose of physical activity, and should be considered in future work.

Future Recommendations

It is clear that there needs to be more studies that inform choice regarding methodological decisions about measuring physical activity. Optimum daily wearing of activity monitors required for accurate measurement, the selection

of appropriate variables produced by monitors and the application of combined accelerometry and self-report are all worthy of further exploration.

These data, alongside that of other studies, raise the question of whether longer-term support during an intervention is likely to lead to greater improvements in physical activity. In the current trial, SPACE FOR COPD was only formally supported for the first four weeks. Additionally to trends observed in physical activity, there were changes in other outcomes which were significant at six weeks but not by six months. Therefore it may be worthwhile for future work in SPACE FOR COPD to test the effectiveness of longer-term follow-up support.

The measurement of time spent over 3 METs in at least 10 minute bouts is a novel approach to measuring and reporting physical activity monitor data in COPD studies. It permits for the interpretation of how well a population adheres to the recommended weekly amount of physical activity. The data from this trial suggests that 150 minutes may be unachievable for many people with COPD. There may be some value in future research establishing an optimum amount of activity for this population.

Conclusions

There were significant improvements in step count at six weeks, however no statistically significant changes in physical activity were maintained at six months. This finding is in keeping with several other trial outcomes (chapters 4 and 5). Overall this may suggest that SPACE FOR COPD was most

effective during the first six weeks, when planned support was provided. Deducing who is likely to improve in physical activity was not possible with the data that was available from this study. Interestingly, however, exercise capacity, knowledge or self-efficacy were not significant in a model to predict change in physical activity.

Chapter 8 General Discussion

The aim of this thesis was to conduct an RCT to test the effectiveness of SPACE FOR COPD in primary care in the UK. SPACE FOR COPD is a new programme of self-management which aims to support core self-management skills and teach disease specific tasks which enables the individual to improve their quality of life as a result of changing health promoting behaviours.

The hypothesis was that SPACE FOR COPD would confer a greater benefit on HRQoL when compared with usual care alone. In addition to HRQoL, we also sought to explore the impact of SPACE FOR COPD on knowledge, self-efficacy, exercise performance, psychological function and physical activity. The discussion will be divided into main findings, study limitations, future work and final conclusions.

8.1 Main Findings

The hypothesis that SPACE FOR COPD would improve dyspnoea significantly more than usual care at six months was not supported by the data in this trial. Dyspnoea in both the intervention and control groups improved at six months (chapter 5). Upon reflection, it might have been more appropriate to appoint the primary outcome as the change in CRQ-SR dyspnoea at six weeks rather than six months. It is well documented that changes in HRQoL following pulmonary rehabilitation improves over the short-term of six to eight weeks, but can diminish during the follow-up period at six

months (Egan et al. 2012; Sewell et al. 2006). Six weeks was considered to be the 'intervention period' of SPACE FOR COPD and the minimum amount of time required for changes in clinical outcomes to take place. A primary outcome of the intervention period would have been more appropriate, with secondary outcomes at six months to evaluate the maintenance period.

There were short-term advantages in the SPACE FOR COPD group in HRQoL, anxiety, exercise performance knowledge and step count (chapters 4 and 7). This is the first study to document changes in such an array of outcomes over such a short time frame. This has implications for recognising the variety of outcomes which need to be measured and how early changes can occur following initiation of self-management support.

In the medium-term, significant improvements in endurance exercise performance and anxiety were maintained at six months (chapter 5). For those at risk of depression, depression scores on the HADS showed continued improvement in the SPACE FOR COPD group, and at six months the mean difference between groups exceeded the MCID, although this was not statistically significant. This is the first self-management study to demonstrate maintenance of exercise performance over such a period following an unsupervised programme of exercise training, and is also the first self-management study to document changes in depression of this magnitude. Maintenance of improvements in walking performance and emotional status are important clinical outcomes for people living with COPD.

The patients recruited to this study were largely managed in primary care. COPD patients in primary care are substantially under researched, compared with those managed in secondary or tertiary care. This thesis, therefore, has added a novel insight into a population of people with COPD that we currently have a lack of understanding of. It might have been anticipated that because these patients seem to manage better by avoiding the need for secondary care contact that physical activity levels may have been relatively well preserved. However, compared with other studies of healthy populations, physical activity levels in this population are low (chapter 6). Given the association of low activity and poor health outcomes, this highlights the need for an intervention aimed at improving physical activity in these patients.

In this thesis the opportunity was taken, as the first UK-based study, to evaluate the adherence of a sample of COPD patients to the guidelines for physical activity (chapter 6). This provides insight into the magnitude of the problem of physical inactivity in COPD and highlights important methodological issues in physical activity monitoring. Moreover, this is the first self-management study to measure physical activity in response to an intervention by using validated and reliable accelerometers (chapter 7). This is an important advance in the field, given that behaviour change is a key aim of self-management, and that physical activity is an important behaviour in COPD and the focus of many sophisticated interventions.

There are several implications and caveats to these findings which will be discussed within relation the population and the intervention.

8.1.1 The Population

This is one of only two self-management studies globally, which have specifically targeted an intervention to patients managed in primary care. The other study evaluated a practice nurse-led education intervention, with no exercise and found no significant impact on either the primary measure of CRQ-SR or secondary measures of self-efficacy and healthcare utilisation (Bischoff et al. 2012). The present study, therefore, is the first study of a self-management programme in primary care which has show significant clinical benefits. In this study, it is likely that targeting SPACE FOR COPD towards a primary care population in the UK has had several implications on the findings.

The delivery of SPACE FOR COPD early within the course of the disease may be important in understanding what differentiates SPACE FOR COPD from other studies. Many studies have targeted self-management support towards patients who have previously been hospitalised with a COPD related admission (Bourbeau et al. 2003; Bucknall et al. 2012; Fan et al. 2012; Rice et al. 2010). Two such studies published recently have had poor outcomes, with one study showing no impact of the self-management programme at all (Bucknall et al. 2012), while the other was stopped prematurely due to safety concerns due to higher mortality in the treatment arm (Fan et al. 2012). There may be several reasons why self-management post-exacerbation has not been more successful.

The rationale that self-management support for those who have been hospitalised for their COPD should be effective is based in theory. The Health Belief Model (Becker 1974) and the Protection Motivation Theory (Rogers 1975) dictate that people will not be motivated to change behaviour unless they feel a direct threat. In COPD, this is likely to be an acute event, such hospitalisation due to exacerbation. People who have been admitted to hospital due to COPD may feel at their most vulnerable at this time, and may be more motivated to change negative health behaviours, such as smoking and physical inactivity. However, in this instance, the increased threat of the exacerbation is usually only temporary, and once the symptoms of the exacerbation are relieved, motivation levels may decline.

A recent study reported the natural history of COPD in a Canadian population and identified the importance of the negative impact of hospitalisation on disease progression (Suissa, Dell'Aniello, and Ernst 2012). The paper proposed from their data that there was around a five year lag between the first and second hospitalisation, and after the second, hospitalisations for COPD became more frequent and regular. Self-management strategies may be too subtle to make a significant impact in patients who are already entrenched within the spiral of disability associated with frequent hospitalisations. Self-management support aims to address behaviours to optimise medical and emotional well-being. These behaviours may be modified more readily in individuals who are earlier within the disease process and less burdened by frequent exacerbations and disease symptoms which may make it difficult to sustain behaviour change.

The present study recruited patients who were largely managed in primary care, and were mostly MRC grade 2. In contrast to some other programmes, SPACE FOR COPD may have been more effective as it was directed towards patients who were less functionally impaired and entrenched within the spiral of disability. These patients, therefore, may have found it easier to adopt new skills and tasks. Furthermore, having predominantly only been managed within primary healthcare for their COPD, these patients were perhaps likely to be have less knowledge about COPD and many self-management strategies. Usually, other than inhaled therapy, primary care offers little further treatment options for COPD, particularly early in the disease. These patients, therefore, were likely to have the most to gain from SPACE FOR COPD, given that previous input or advice was likely to be low.

It may, however, still not be early enough. In other disease self-management programmes, such as diabetes, self-management support is routinely delivered soon after diagnosis (Davies et al. 2008). One study in diabetes self-management reported time since diagnosis was the most important factor for predicting a positive outcome (Ko et al. 2012). This suggests that the sooner self-management was delivered within the course of the disease the more likely changes in behaviour would be adopted. While the present study aimed to target individuals early within the disease, we did not seek to recruit newly diagnosed patients. The literature from the diabetes studies suggests that there may be additional benefits from initiating self-management support even earlier than in this study, and perhaps soon after the point of diagnosis.

The argument for self-management support for those earlier within the course of their disease is strengthened when considering the data presented in chapter 6, which showed that that physical activity levels were impaired in this population, in comparison with healthy counterparts. This suggests that although patients who are MRC grade 2 might be considered to be at the 'better' end of the COPD spectrum, they may already have adjusted their behaviour in response to their COPD. This highlights the need for an intervention to promote positive behaviour change in patients who are less disabled by their disease. Particular consideration should be given to this when we consider that pulmonary rehabilitation, which is the only form of self-management support regularly provided in the UK, is only usually offered for those who score 3 or higher on the MRC scale. SPACE FOR COPD may be a suitable self-management approach to be delivered to patients earlier within the course of their disease, in order to provide behaviour change support to those who would otherwise have had nothing.

The importance of early intervention is amplified when we consider the progressive decline in functional capacity and health outcomes over time, which have been well documented in people with COPD (Agarwal et al. 2012; Casanova et al. 2007). In the face of an incurable disease, prevention of further decline may be the most hopeful option. Preservation of the status quo, in terms of health status, may be considered a positive outcome in light of the progressive disease burden. Negative health behaviours, namely smoking, exercise intolerance and physical inactivity, are significantly associated with worse health outcomes (Celli et al. 2004; Godtfredson et al.

2008; Waschki et al. 2011). SPACE FOR COPD aims to have a positive impact on these behaviours, and the results from this trial suggest that the intervention is successful in improving some of these changes. However, a positive result from a behavioural intervention may not be improvement, but may be maintenance instead. Preservation of health status may therefore be the ultimate aim of SPACE FOR COPD. Longer-term follow-up is required in order to evaluate how well and how long outcomes are maintained following SPACE FOR COPD, in the face of a disease which progressively deteriorates.

While initiation of self-management support early within the course of the disease may be preferable, it may be a challenging ambition given the high prevalence of undiagnosed COPD (Bastin et al. 2010). A recent study in the UK suggested that around 34% of people admitted to a general district hospital due to COPD had not previously been diagnosed with the disease (Bastin et al. 2010). Moreover, the mean (SD) FEV_1 of these patients was severe at 1.02 (0.32) litres. This highlights that people with COPD do not present early, and may not even be identified in primary care. In order to provide self-management support early within the disease, screening or case finding programmes must be employed, as outlined in the UK government's agenda (Department of Health 2012b).

8.1.2 The Intervention

The NHS outcomes framework has identified in domain 2 that one of the key topics on the political health agenda for 2013/14 in the UK is enhancing

quality of life for people with long-term conditions (Department of Health 2012b), and that self-management will play a role in meeting this aim (Department of Health 2012a). One of the challenges of providing self-management support to a whole population of people with COPD is to develop an intervention which is both effective yet capable of being able to meet the demand. Given there may be around three million people in the UK with COPD, this presents a considerable challenge (Stang et al. 2000). Some self-management programmes to date have provided heavily supervised programmes, with one-to-one home visits (Bourbeau et al. 2003; Boxall et al. 2005), loaning exercise equipment (Maltais et al. 2008), or supervised physical training for up to two years (Monninkhof et al. 2003). In the current financial and political climate in the UK it is not feasible to implement these kinds of programmes to the breadth of the COPD population, and they are therefore unlikely to be commissioned. At the other end of the spectrum, the simplest form of self-management is the provision of an action plan or brief education. There is, however, little evidence that these programmes have any clinical benefit (McGeoch et al. 2006; Watson et al. 1997). SPACE FOR COPD adopts a light-touch approach which would be feasible to roll out nationwide, although the content is comprehensive and encompasses all core self-management skills. SPACE FOR COPD is therefore not only an effective programme of self-management, but has potential to be deliverable on a larger scale than other models of self-management.

We might suppose that light-touch interventions may be less effective than more heavily supervised approaches. There might be an assumption that self-

management skills may be learned more easily if practiced under the supervision of a healthcare professional, and that there may be a dose-response between the level of support provided and the outcome of the intervention. However the findings from this study, in comparison with other self-management programmes, do not support this hypothesis. There may be a number of explanations why the light-touch approach of SPACE FOR COPD challenges these assumptions.

Individuals on SPACE FOR COPD were required to learn self-management skills in a self-directed manner, within their own home environment. Learning within one's own environment may enable individuals to develop skills and practice them in the way in which they mean to continue using them. We might anticipate that this would more easily allow for maintenance of skills and therefore sustained behaviour change. This is in contrast to supervised courses, whereby individuals learn skills within a foreign environment and have the option rely upon a healthcare professional for support. In a supervised environment it may be easier to revert to more traditional, paternalistic patient healthcare professional roles.

It is important to consider the participants' expectations of those undertaking the SPACE FOR COPD intervention. Patients undergoing a supervised course expect a course which lasts for a specified duration and has an end point. Conversely, on SPACE FOR COPD, patients are encouraged to think of it as lifestyle intervention, and no end point of the programme is predefined. This may mediate patient expectations from the start and may influence

attitudes as to how long behaviour changes are to be maintained. From the outset, patients may therefore anticipate that these are lifestyle changes, rather than changes to be made solely for the duration of a course.

Although the qualitative data from this trial has not been reported in this thesis, a key finding from patients who were interviewed that had used the manual was that patients felt that the telephone support was considerably reassuring. A qualitative study of telephone support reported many advantages to regular telephone contact (Walters et al. 2012). Patients reported that it acted as a 'regular reminder' and reinforced health behaviours, it helped to create a partnership with the healthcare professional and patients developed a sense of responsibility to them. Patients also identified that the knowledge that they would be receiving a call was a motivating factor and reassuring. While it is not possible to evaluate to what extent the phone contact contributed to the positive impact of the intervention, in the absence of any direct face-to-face healthcare supervision, the telephone contact might have been a valuable feature. The lack of contact between six weeks and six months may, in part, be a reason for the lack of maintenance in some of the outcomes in this trial. This might be addressed in further research.

One of the challenges in making comparisons between the present study and others is the different duration of interventions and the different time to follow-up. Other studies have had longer intervention periods and have therefore not conducted assessments until between three and seven months (Bourbeau et al. 2003; Effing et al. 2011; Monninkhof et al. 2003). If the intervention period

and time to follow-up is longer then the opportunity to measure the potentially greater, short-term response is missed. This means it is difficult to identify whether greater changes were made that then declined, and whether strategies to support maintenance should be employed.

8.2 Study Limitations

The data presented in chapters 4 and 5 demonstrates that there was a significant improvement in the CRQ-SR dyspnoea domain in both the intervention and usual care groups. This change in the usual care group was not anticipated. While no additions were made to usual care, the significant improvements in dyspnoea suggest that some impact had occurred in this group as a result of participating in the trial. Firstly, there is the impact of receiving attention, which is a well-known effect and is often referred to as the Hawthorne effect after the famous Hawthorne experiments (Landsberger 1958). Secondly, the actual completion of maximal exercise tests may also have a significant impact on the patient (van Sluijs et al. 2006). In other disease populations, the performance of exercise tests has been shown to improve mood (Ewart et al. 1983) and increase confidence in undertaking physical tasks (O'Connor et al. 1995). For individuals with COPD, performing a maximal exercise test with a healthcare professional may be a liberating experience, as individuals experience exertion beyond what they previously though possible, without any detrimental effects.

This raises the debate of to what extent is does the assessment itself become part of the intervention? In this study, given that the participants were

managed in primary care and had previously received little attention for their COPD, the impact of the assessment itself might have been considerable. Each assessment took between one and two hours, and was conducted in a hospital, by a physiotherapist who specialises in COPD. While every effort was made to minimise the potential impact of these assessments, it seems likely that these patients who had been relatively naïve to their condition and had sought to enrol in a research study for their disease, gained some positive effect of the assessments.

In future work, this issue may be difficult to navigate if we wish to establish the effect on exercise performance. The Solomon-4 design trial has been described to manage this problem (McCambridge et al. 2011). It requires a four-group design whereby each randomised group is randomised a second time to either undergo or no undergo an assessment. This allows the effects of the intervention to be distinguished from the effects of assessment. If this design had been used in this study, it might have been easier to evaluate the real between-group difference between intervention and usual care. The Solomon-4 design, however, has not been used frequently and does require a larger sample size, which may pose difficulties. Conduct of the exercise tests by a technician, rather than a specialist, may also help to minimise the impact of the walking tests.

Additionally, the term ‘demand characteristics’ has been applied to the phenomenon whereby participants are aware of the research aims, anticipating the findings and what this implies for how they are expected to

behave (McCambridge et al. 2012). In the present study, all participants were aware that investigators were testing the impact of a self-management manual which included education and exercise training on HRQoL, exercise performance and physical activity. It was clear to participants from the patient information sheet (appendix 4) that the investigators anticipated a positive impact. It is therefore possible that participants randomised to usual care who did not receive SPACE FOR COPD may have sought their own education and exercise regime, in the understanding that would have a positive impact. Demand characteristics may be challenging to negotiate around, however one possibility is the opportunity to carry out concealed consent. This method of consent withholds the purpose or aims of the study from participants until after the trial has finished, therefore reducing the risk of this effect. This has been seldom reported, however, and may have significant ethical implications.

When we consider the transtheoretical model of change (figure 8.1), we can see that relapse is a part of the process of change (Prochaska and DiClemente 1983). It should be expected, therefore, that sustained behaviour change will not be achieved by all. In this study, the lack of contact following the four-week phone call meant that there was no opportunity to support patients who entered the relapse phase. A recent study evaluated a counselling intervention whereby GPs provided a single motivational interviewing consultation aimed at provoking behaviour change in smoking, drinking, unhealthy eating or physical inactivity ((Butler et al. 2013). The study showed that there was no beneficial outcome at 3 months, and suggested that behaviour change was unlikely to occur after a single consultation. The study

did show that there was an improvement in attempts to change and the patients' perceptions of having made a change at three months. The SPACE FOR COPD study did not evaluate attempts to change, which may have been insightful information. Furthermore, the findings from Butler et al. suggest that one MI consultation may not be enough. Regular contact from the supporting healthcare professional would allow better support for patients who relapse, permitting the opportunity to use MI again to continue along the cycle.

Figure 8.1 Transtheoretical Model of Change (Prochaska and DiClemente 1983)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

In this study SPACE FOR COPD was delivered as part of a research process, and as usual, subject selection bias whereby the participants recruited were likely to be the more motivated and willing patients. In routine practice not all

patients will be as motivated. Given the self-directed nature of the intervention this may mean that SPACE FOR COPD is not beneficial for all people with COPD. It will be important in future work to identify who is most likely to benefit from SPACE FOR COPD and treatment options can therefore better be directed. Ultimately, chronic disease care should be personalised to the individual rather than a 'one size fits all' approach, therefore it is unlikely SPACE FOR COPD will suit everyone. SPACE FOR COPD, however, adds to the menu of treatment options available, which up until now have been limited.

SPACE FOR COPD is a multifaceted, complex intervention, and is comprised of the SPACE FOR COPD manual, the interaction between the patient and the healthcare professional, motivational interviewing and telephone support. It is not possible to derive from this study which aspects of the intervention were the most helpful and which were the least. Furthermore, it was not possible to explore how well the programme was followed by any of the participants. The engagement required by the patients could not be either demanded or measured. It is therefore not possible to tell whether some patients 'took the pill' as it were. This means it is not possible to evaluate whether there was a dose response, or to re-evaluate the programme and revise it based on how well it is used. In this particular model of SPACE FOR COPD this may continue to be difficult to measure. However, as the SPACE FOR COPD programme is remodelled onto a website (www.spaceforcopd.co.uk), the data obtained from this will give us far more insight into how much the programme is used and which aspects are used.

The website will offer a more sophisticated, technology-based solution to self-management for COPD, broadening the modes of delivery suited to different learning styles.

Co-morbidities in COPD are common (van der Molen 2010), and have been associated with worse quality of life and reduced capacity for activities of daily living (Yeo et al. 2005). The trial design in this thesis excluded participants who would be unable to conduct the exercise programme; however, it is likely there were a number of other patients who were included who had at least one co-morbidity. The capacity for patients with multiple morbidities to undertake SPACE FOR COPD may have been restricted; however, this was not addressed in this thesis. It is, therefore, not possible to evaluate to what extent multiple morbidities may have influenced the outcomes of this trial. The EPP is a self-management programme aimed to all chronic diseases, and may therefore be better equipped to consider co-morbidities. Evidence to date, however, suggests that it does not improve disease-specific behaviours, such as exercise capacity or dyspnoea which may be important outcomes for people with COPD (Wright et al. 2003; Barlow et al. 2005a). For individuals, where the symptoms of COPD are the primary cause of disability, a disease-specific programme like SPACE FOR COPD might be the most appropriate form of self-management support, in order to improve important clinical outcomes. Individuals with co-morbidities which are equally disabling might have more to gain from a more general self-management course, such as the EPP.

Finally, this trial was not sufficiently powered for all of the secondary outcomes, and the number of comparisons made was not corrected for. By conducting a large number of comparisons there is increased risk of type I error. However, methods of correction, such as the Bonferroni adjustment increase the risk of type II error. This study is, however, powered on the primary outcomes of the CRQ-SR dyspnoea domain, and it is upon that measure that the hypothesis of this study is rejected. Secondary outcomes in this trial are to be treated cautiously, and are for exploratory purposes only. A similar pattern is seen in the data across many of the secondary outcome measures, suggesting an improvement in the SPACE FOR COPD group compared with usual care. These data provide an adequate enough basis to generate hypotheses to inform future studies.

8.3 Areas for Further Research

Implementation

This thesis describes the first fully powered RCT designed to establish the effectiveness of SPACE FOR COPD. This followed a rigorous development procedure and feasibility and pilot testing of the intervention. In line with the MRC guidelines for complex interventions (figure 8.2), the next phase is to implement the research findings. The aim of the implementation phase of the process is to evaluate how well SPACE FOR COPD can be delivered outside of the 'research' environment described in this trial, and in more of a 'real-life' clinical setting. A training programme which is comprised of on-line learning and a face-to-face workshop has been developed and tested in order to equip healthcare professionals with the knowledge and expertise required to deliver

and support patients on SPACE FOR COPD. Future research should evaluate the effectiveness of SPACE FOR COPD, delivered by healthcare professionals who have undertaken the training, on a larger sample of patients across multiple sites. The findings from this kind of research would be more generalisable to the wider population.

Figure 8.2 Guidelines for complex interventions (Medical Research Council 2008)

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Maintenance strategies

Prior to, or alongside, an implementation project, there may be adjustments or modifications to the intervention which should be considered. The findings from this study suggest that short-term gains are not wholly maintained in the medium-term without any form of on-going support. The chronic care model suggests that self-management should sit within a wider system of integrated care (Wagner 1998), and that components of the CCM are more effective when used in conjunction (Adams et al. 2007). It seems warranted, therefore, to evaluate the impact of the addition of longer-term support following SPACE

FOR COPD beyond the four-week telephone contact. This could be in the form of telephone support, which as discussed in section 8.1 has previously been reported as advantageous (Walters et al. 2012). Furthermore, if SPACE FOR COPD is embedded in primary care, and is provided by the practice nurse, there will automatically be regular on-going collaboration between the patient and the practice nurse.

Group-based delivery

There may be some additional benefits to group-based delivery of SPACE FOR COPD. Self-management programmes in other diseases which have used a group-based approach have had moderate long-term success (Barlow et al. 2009; Khunti et al. 2012; Rickheim et al. 2002; Tang et al. 2012a; Tang et al. 2012b) and reported that evaluation of the group dynamics has been important for its success (Harrison et al. 2011). The Chronic Disease Self-management Programme (CDSM), or the EPP in the UK, is a group-based, lay-led self-management course for a range of chronic diseases. There have been a number of studies conducted which have demonstrated that the course is moderately effective in improving self-efficacy and is probably cost-effective also (Barlow et al. 2005a; Kennedy et al. 2007; Wright et al. 2003). The evidence so far suggests that benefits from the EPP are largely psychological gains, in terms of cognitive management, symptom management and self-efficacy (Wilson et al. 2007; Wright et al. 2003). COPD-specific outcomes, such as exercise performance, dyspnoea or physical activity, which are critical to long-term health outcomes, have not been

measured objectively, and self-reported data have shown no improvement following the EPP (Barlow et al. 2005a; Wright et al. 2003).

Patients have rated the EPP highly, and have reported that group-work enhances motivation, is reassuring, and increases confidence and control (Barlow et al. 2005b). Social Learning Theory suggests that people will alter their behaviour based on the behaviour they observe of other people, or 'models', around them (Bandura 1977b). Group members may make positive changes by modelling their own behaviour on that of others in the group who they aspire to. However, a recent study which evaluated the impact of social comparisons on anxiety in a pulmonary rehabilitation group-setting found that making upward social comparisons did not improve anxiety (Peterson et al. 2012). Downward social comparisons, however, were more likely to increase anxiety as patients saw other people who they perceived as 'worse' than them, and viewed that to be their future (Peterson et al 2012). Additionally, group-based self-management may be hampered by 'problem-patients' who do not engage well with the self-management programme and have been identified as disruptive of group dynamics (Wilson et al. 2007). It is indeed likely that there are pros and cons to group-based self-management delivery, and different approaches will be required to meet the varied learning styles and needs of every individual. Indeed, it may be best to shift away from trying to identify the 'ideal' method of delivery, and move instead towards a menu of options, individualised and tailored to each patient.

Personalised Care

This shift may be best described as 'personalised care'. There are now a range of approaches for providing self-management support for people with COPD (appendix 2/ Wagg 2012). Furthermore, a new web-based version of SPACE FOR COPD has also been developed and is currently being evaluated. Given the menu of treatments available, and in-line with current opinions on individualised care, evaluation of a patient-tailored approach to care is warranted. A trial which used a decision-tree to direct patients to SPACE FOR COPD, the web programme, pulmonary rehabilitation, or a group-based programme would be novel, and would mimic more of a 'real-life' approach to individualised patient care. It might be anticipated that if the method of support has been individualised rather than prescribed as a 'one size fits all' approach then it may be more effective.

SPACE FOR COPD vs. pulmonary rehabilitation

The capacity for pulmonary rehabilitation and uptake for the course is low. In 2008 only 15% of eligible participants in the UK had completed the course (The Royal College of Physicians, The British Thoracic Society and The British Lung Foundation 2008). Reasons for not attending pulmonary rehabilitation, despite its well-known benefits (Lacasse et al. 2006), are varied. SPACE FOR COPD might seem like a reasonable alternative to pulmonary rehabilitation in the instance that people cannot attend. SPACE FOR COPD might be a practical alternative for people who live in rural areas, have difficulty with transportation or care for their spouse or other family members. While the impact on HRQoL and maximal exercise capacity

described in this thesis are not as great as changes documented from pulmonary rehabilitation (Sewell et al. 2005; Evans et al. 2010), for those who would otherwise receive nothing, it might be the next best alternative. This will be evaluated in future research trials.

After First Hospitalisation

There are substantial financial consequences of hospital admissions (Healthcare Commission 2006) and there is extensive pressure on NHS trusts to reduce re-admissions. The concern of admissions is also of interest to primary care as the median number of visits to GPs in the 12 months prior to admission in the 2008 COPD audit was 12 (The Royal College of Physicians, The British Thoracic Society and The British Lung Foundation 2008), indicating the high usage of primary care prior to admission.

Although the most ideal time to provide self-management might be following early diagnosis within primary care, many patients are diagnosed upon their first hospital admission for a COPD exacerbation (Bastin et al. 2010). A recent study by Suissa, Dell'Aniello, and Ernst (2012) suggested that on average, there may be around five years between the first and second hospitalisation for a COPD exacerbation. Following the second, hospitalisations become more frequent. Although post-exacerbation self-management interventions have not generally been effective (Bucknall et al. 2012; Fan et al. 2012), the work by Suissa and colleagues suggest that if self-management might be at all effective post-hospitalisation, then after the first episode is likely to be more successful than after several admissions. For

some patients who have had their first exacerbation which required hospitalisation, it may be an ideal opportunity to address behaviour change as this is a time when a patient might be most likely to be motivated to change through experience of the negative consequences of their behaviour (Becker 1974; Rogers 1975). SPACE FOR COPD may be useful in supporting patients in behaviour changes, such as smoking cessation, exercise training or physical activity uptake, and evaluation of SPACE FOR COPD following first hospitalisation due to COPD should be addressed in the future.

Health economics

It is anticipated that there may be financial gains if an individual who self-manages resumes a greater responsibility for self-care and becomes less reliant upon healthcare services (Department of Health 2012a). Many self-management studies, therefore, have conducted economic analyses alongside clinical effectiveness data (Bourbeau et al. 2006; Khdour et al. 2011; Monninkhof et al. 2004b). Most healthcare systems around the world face considerable financial challenges, and with the current system of commissioning in the NHS, interventions that show a cost-effective benefit may seem more likely to be implemented into clinical care. There are a number of approaches which can be taken to economic analysis and they may be to assess cost-effectiveness or cost-utility. Alongside this trial healthcare utilisation data and medication usage has been collected directly from GP and hospital databases and an accurate account of intervention-related costs have been kept in order to perform such analyses. A full cost-effective or cost-utility analysis was deemed too large to fall under the remit of

this thesis, however expertise has been sought to assist with these analyses and are being conducted by the research team. It is anticipated these data will be published following the publication of the clinical findings.

8.4 Final Conclusions

The aim of this thesis was to test the effectiveness of SPACE FOR COPD as an independent self-management intervention for people with COPD in primary care. It was anticipated that SPACE FOR COPD would provoke changes in health behaviours and lead to improved patient outcomes when compared with usual care alone. This study has shown that SPACE FOR COPD was not effective in improving dyspnoea over and above usual care at six months. Secondary findings suggest that there were short-term gains in HRQoL, exercise performance, psychological status, disease knowledge and steps when using SPACE FOR COPD. Improvements in exercise performance and psychological well-being were maintained after six months. Despite the rejection of the study hypothesis, the results of the secondary measures suggest that there may be some benefits to SPACE FOR COPD above usual care.

SPACE FOR COPD adopts a light-touch approach, which may make it favourable for implementation as a self-management strategy for primary care in the UK. This is in contrast to many studies which have provided more highly supervised programmes. Despite being light-touch, SPACE FOR COPD does demonstrate clear benefits, unlike other light-touch interventions such as action plans.

This thesis has focused on patients managed largely in primary care, who have previously been under-researched in self-management. Observing this group of patients has given unique insights into physical activity levels in patients who appear to manage their disease well. The work in this thesis has highlighted the need for interventions aimed at improving physical activity and promoting self-management in patients who are less functionally limited by their disease.

There are numerous opportunities for future research. Some of these relate directly to the intervention, such as evaluating group-based delivery, the additional benefit of on-going support, effectiveness following first hospitalisation and the economic benefits of the programme. Other questions relate to the methodology, such as whether there is an effect of a research assessment, or conducting an exercise test. It is anticipated that many of these opportunities can be explored in the future in order to enhance our understanding of the usefulness of SPACE FOR COPD and in improving the care for people with COPD.

References

Adams, S.G., Smith, P.K., Allan, P.F., Anzueto, A., Pugh, J.A., and Cornell, J.E. (2007) 'Systematic review of the chronic care model in chronic obstructive pulmonary disease prevention and management'. *Archives of Internal Medicine* 167 (6), 551-561

Agarwal, V., Tetenta, S., Bautista, J., ZuWallack, R., and Lahiri, B. (2012) 'Longitudinal changes in directly measured physical activity in patients with chronic obstructive pulmonary disease: the trajectory of change'. *Journal of Cardiopulmonary Rehabilitation and Prevention* 32 (5), 292-295

Ajzen, I. (1991) 'The theory of planned behavior'. *Organizational Behaviour and Human Decision Processes* 50 (2), 179-211

Akl, E.A., Briel, M., You, J.J., Sun, X., Johnston, B.C., Busse, J.W., Mulla, S., Lamontagne, F., Bassler, D., Vera, C., Alshurafa, M., Katsios, C.M., Zhou, Q., Cukierman-Yaffe, T., Gangji, A., Mills, E.J., Walter, S.D., Cook, D.J., Schunemann, H.J., Altman, D.G., and Guyatt, G.H. (2012) 'Potential impact on estimated treatment effects of information lost to follow-up in randomised controlled trials (LOST-IT): systematic review'. *British Medical Journal* [online] 344, e2809. available from <http://www.bmj.com/content/344/bmj.e2809> [April 2013]

Anthonisen, N.R. (1989) 'Prognosis in chronic obstructive pulmonary disease: results from multicenter clinical trials'. *American Review of Respiratory Disease* 140 (3 Pt 2), S95-S99

Anthonisen, N.R., Manfreda, J., Warren, C.P., Hershfield, E.S., Harding, G.K. and Nelson, N.A. (1987) 'Antibiotic therapy in exacerbations of chronic obstructive pulmonary disease'. *Annals of Internal Medicine* 106 (2), 196-204

Azur, M.J., Stuart, E.A., Frangakis, C. and Leaf, P.J. (2011) 'Multiple imputation by chained equations: what is it and how does it work?'. *International Journal of Methods in Psychiatric Research* 20 (1), 40-49

Bailey, P.H. (2004) 'The dyspnea-anxiety-dyspnea cycle - COPD patients' stories of breathlessness: "It's scary when you can't breathe" '. *Qualitative Health Research* 14 (6), 760-778

Bandura, A. (1977a). 'Self-efficacy: toward a unifying theory of behavioral change'. *Psychology Review* 84 (2), 191-215

Bandura, A. (1977b) *Social Learning Theory* [online] Englewood Cliffs NJ: Prentice Hall. available from <http:www.jku.at/org/content/e54521/54528/e54529/e178059/Bandura_SocialLearningTheory_ger.pdf> [April 2013]

Barlow, J., Turner, A., Swaby, L., Gilchrist, M., Wright, C. and Doherty, M. (2009) 'An 8-yr follow-up of arthritis self-management programme participants'. *Rheumatology (Oxford)* 48 (2), 128-133

Barlow, J.H., Wright, C.C., Turner, A.P. and Bancroft, G.V. (2005a) 'A 12-month follow-up study of self-management training for people with chronic disease: are changes maintained over time?'. *British Journal Health Psychology* 10 (Pt 4), 589-599

Barlow, J.H., Bancroft, G.V., and Turner, A. P. (2005b) 'Self-management training for people with chronic disease: a shared learning experience'. *Journal of Health Psychology* 10, 863-872

Barlow, J., Wright, C., Sheasby, J., Turner, A. and Hainsworth, J. (2002) 'Self-management approaches for people with chronic conditions: a review'. *Patient Education and Counseling* 48 (2), 177-187

Bastin, A.J., Starling, L., Ahmed, R., Dinham, A., Hill, N., Stern, M. and Restrick, L.J. (2010) 'High prevalence of undiagnosed and severe chronic obstructive pulmonary disease at first hospital admission with acute exacerbation'. *Chronic Respiratory Disease* 7 (2), 91-97

Becker, M.H.(1974) 'The health belief model and personal health behavior'. *Health Education Monographs* 2, 4

Bensten, S.B., Henriksen, A.H., Wentzel-Larsen, T., Hanestad, B. R., and Wahl, A. K. (2008) 'What determines subjective health status in patients with chronic obstructive pulmonary disease: importance of symptoms in subjective health status of COPD patients'. *Biomed Central Health and Quality of Life Outcomes* [online] available from <http://www.hqlo.com/content/6/1/115> [April 2013]

Bischoff, E.W., Akkermans, R., Bourbeau, J., van, W.C., Vercoulen, J.H. and Schermer, T.R. (2012) 'Comprehensive self management and routine monitoring in chronic obstructive pulmonary disease patients in general practice: randomised controlled trial'. *British Medical Journal* [online] 345, e7642. available from <http://www.bmj.com/content/345/bmj.e7642> [April 2013]

Blanc, P.D. and Toren, K. (2007) 'Occupation in chronic obstructive pulmonary disease and chronic bronchitis: an update'. *International Journal of Tuberculosis and Lung Disease* 11 (3), 251-257

Bodenheimer, T., Lorig, K., Holman, H. and Grumbach, K. (2002) 'Patient self-management of chronic disease in primary care'. *Journal of the American Medical Association* 288 (19), 2469-2475

Borg, G. (1982) 'Ratings of perceived exertion and heart rates during short-term cycle exercise and their use in a new cycling strength test'. *International Journal of Sports Medicine* 3 (3), 153-158

Bourbeau, J. (2008) 'Clinical decision processes and patient engagement in self-management'. *Disease Management and Health Outcomes* 16 (5), 327-333

Bourbeau, J., Collet, J.P., Schwartzman, K., Ducruet, T., Nault, D. and Bradley, C. (2006) 'Economic benefits of self-management education in COPD'. *Chest* 130 (6), 1704-1711

Bourbeau, J., Nault, D. and Dang-Tan, T. (2004) 'Self-management and behaviour modification in COPD'. *Patientient Education andCounseling* 52 (3), 271-277

Bourbeau, J., Julien, M., Maltais, F., Rouleau, M., Beaupre, A., Begin, R., Renzi, P., Nault, D., Borycki, E., Schwartzman, K., Singh, R. and Collet, J.P. (2003) 'Reduction of hospital utilization in patients with chronic obstructive pulmonary disease: a disease-specific self-management intervention'. *Archives of Internal Medicine* 163 (5), 585-591

Bourdin, A., Vachier, I., Godard, P. and Chanez, P. (2009) 'Airway wall structural remodeling from endobronchial biopsies: what does it really mean?'. *Journal of Allergy and Clinical Immunology* 123 (3), 711-712

Boxall, A.M., Barclay, L., Sayers, A. and Caplan, G.A. (2005) 'Managing chronic obstructive pulmonary disease in the community. A randomized controlled trial of home-based pulmonary rehabilitation for elderly housebound patients'. *Journal of Cardiopulmonary Rehabilitation* 25 (6), 378-385

Braido, F., Baiardini, I., Menoni, S., Maria, B.A., Balbi, F., Bocchibianchi, S., Balestracci, S., Grazia, P.M. and Walter, C.G. (2011) 'Disability in COPD and its relationship to clinical and patient-reported outcomes'. *Current Medical Research and Opinion* 27 (5), 981-6

Breyer, M.K., Breyer-Kohansal, R., Funk, G.C., Dornhofer, N., Spruit, M.A., Wouters, E.F., Burghuber, O.C. and Hartl, S. (2010) 'Nordic walking improves daily physical activities in COPD: a randomised controlled trial'. *Respiratory Research* [online]11: 112 available from < http://respiratory-research.com/content/11/1/112> [April 2013]

British National Formulary (2013) *British National Formulary* [online] available from<http://www.bnf.org/bnf/index.htm> [12 April 2013]

British Thoracic Society (2005) *Spirometry in Practice: A practical Guide to Using Spirometry in Primary Care* 2nd Edn. [online] available from <http://www.brti-thoracic.org/Portals/0/Clinical%20Information/COPD/COPD%20Consortium/spirometry_in_practice051.pdf> [12 April 2013]

Brodie, D.A., Inoue, A. and Shaw, D.G. (2008) 'Motivational interviewing to change quality of life for people with chronic heart failure: a randomised controlled trial'. *International Journal of Nuring Studies* 45 (4), 489-500

Bucknall, C.E., Miller, G., Lloyd, S.M., Cleland, J., McCluskey, S., Cotton, M., Stevenson, R.D., Cotton, P. and McConnachie, A. (2012) 'Glasgow supported self-management trial (GSuST) for patients with moderate to severe COPD:

randomised controlled trial'. *British Medical Journal* [online] 344, e1060. available from <http://www.bmj.com/contnet/344/bmj.e1060> [April 2013]

Bull, F. C. & Expert working group (2010) *Physical Activity Guidelines in the UK: Review and Recommendations* [online] School of Sport, Exercise and Health Sciences, Loughborough University. available from <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/135119/dh_128255.pdf.pdf> [April 2013]

Burge, S. and Wedzicha, J.A. (2003) 'COPD exacerbations: definitions and classifications'. *European Respiratory Journal Supplement* 41, 46s-53s

Butland, R.J.A., Pang, J., Gross, E.R., Woodcock, A.A. and Geddes, D.M. (1982) 'Two-, six-, and 12-minute walking tests in respiratory disease'. *British Medical Journal* 284, 1607-1608

Butler, C. C., Simpson, S.A., Hood, K., Cohen, D., Pickles, T., Spanou, C., McCambridge, J., Moore, L., Randell, E., Alam, M.F., Kinnersley, P., Edwards, A., Smith, C., and Rollnick, S. (2013) 'Training practitioners to deliver opportunistic multiple change counselling in primary care: a cluster randomised trial'. *British Medical Journal* [online] available from <http://www.bmj.com/content/346/bmj.f1191> [April 2013]

Calvert, L.D., Singh, S.J., Morgan, M.D. and Steiner, M.C. (2011) 'Exercise induced skeletal muscle metabolic stress is reduced after pulmonary rehabilitation in COPD'. *Respiratory Medicine* 105 (3), 363-370

Casanova, C., Cote, C.G., Marin, J.M., de Torres, J.P., Aquirre-Jaime, A., Mendez, R., Dordelly, L., and Celli, B.R. (2007) ' The 6-min walking distance: long-term follow up in patients with COPD'. *European Respiratory Journal* 29 (3), 535-540

Cavalheri, V., Donaria, L., Ferreira, T., Finatti, M., Camillo, C.A., Cipulo Ramos, E.M. and Pitta, F. (2011) 'Energy expenditure during daily activities as measured by two motion sensors in patients with COPD'. *Respiratory Medicine* 105 (6), 922-929

Celli, B.R., Thomas, N.E., Anderson, J.A., Ferguson, G.T., Jenkins, C.R., Jones, P.W., Vestbo, J., Knobil, K., Yates, J.C. and Calverley, P.M. (2008) 'Effect of pharmacotherapy on rate of decline of lung function in chronic obstructive pulmonary disease: results from the TORCH study'. *American Journal of Respiratory and Critical Care Medicine* 178 (4), 332-338

Celli, B.R., Cote, C.G., Marin, J.M., Casanova, C., Montes de, O.M., Mendez, R.A., Pinto, P., V., and Cabral, H.J. (2004) 'The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease'. *New England Journal of Medicine* 350 (10), 1005-1012

Cleland, J. A., Lee, A. J. and Hall, S. (2007) 'Associations of depression and anxiety with gender, age, health-related quality of life and symptoms in

primary care COPD patients'. *Family Practice* [online] 24: 217-223 available from <http://fampra.oxfordjournals.org/content/24/3/217.full> [April 2013]

Coleman, K., Austin, B.T., Brach, C. and Wagner, E.H. (2009) 'Evidence on the Chronic Care Model in the new millennium'. *Health Affairs* 28 (1), 75-85

Corbin, J. and Strauss, A. (1988) *Unending work and care: managing chronic illness at home.* San Fransisco: Jossey-Bass

Coronado, M., Janssens, J.P., de, M.B., Terrier, P., Schutz, Y. and Fitting, J.W. (2003) 'Walking activity measured by accelerometry during respiratory rehabilitation'. *Journal of Cardiopulmonary Rehabilitation* 23 (5), 357-364

Creer, T.L. and Holroyd, K.A. (2006) 'Self-management of chronic conditions: the legacy of Sir William Osler'. *Chronic Illness* 2 (1), 7-14

Davies, M.J., Heller, S., Skinner, T.C., Campbell, M.J., Carey, M.E., Cradock, S., Dallosso, H.M., Daly, H., Doherty, Y., Eaton, S., Fox, C., Oliver, L., Rantell, K., Rayman, G. and Khunti, K. (2008) 'Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial'. *British Medical Journal* 336 (7642), 491-495

de Blok, B.M., de Greef, M.H., ten Hacken, N.H., Sprenger, S.R., Postema, K. and Wempe, J.B. (2006) 'The effects of a lifestyle physical activity counseling program with feedback of a pedometer during pulmonary rehabilitation in patients with COPD: a pilot study'. *Patient Education and Counseling* 61 (1), 48-55

Department of Health (2013) *Start active, stay active: A report on physical activity for health from four home countries*. London: Department of Health

Department of Health (2012a) *An outcomes strategy for COPD and Asthma: The NHS Companion Document*. London: Department of Health

Department of Health (2012b) *The NHS Outcomes Framework 2013/2014*. London: Department of Health

Department of Health (2010) C*onsultation on a strategy for services for Chronic Obstructive Pulmonary Disease (COPD) in England*. London: Department of Health

Department of Health (2009) *Chronic Obstructive Pulmonary Disease (COPD) Indicator set: Dataset and Business Rules: new GMS Contract QOF Implemenation. (version14.0)*. London: Department of Health

Department of Health (2004) *Annual report of the Chief Medical Officer on the state of public health.* London: Department of Health

de Voogd, J.N., Sanderman, R., Postema, K., van Sonderen, E., and Wempe, J.B. (2011) 'Relatioship between anxiety and dyspnoea on exertion in patients

with chronic obstructive pulmonary disease'. *Anxiety Stress Coping* 24 (4), 439-449

Donaire-Gonzalez, D., Gimeno-Santos, E., Balcells, E., Rodriguez, D.A., Farrero, E., Batlle, J.D., Benet, M., Ferrer, A., Barbera, J.A., Gea, J., Rodriguez-Roisin, R., Anto, J.M. and Garcia-Aymerich, J. (2012) 'Physical activity in COPD patients: patterns and bouts'. *European Respiratory Journal Express* [online] doi:10.1183/09031936.00101512. available from <http://erj.ersjournals.com/content/early/2012/12/19/09031936.00101512.long > [12 April 2013]

Donaire-Gonzalez, D., Gimeno-Santos, E., Serra, I., Roca, J., Balcells, E., Rodriguez, E., Farrero, E., Anto, J.M. and Garcia-Aymerich, J. (2011) 'Validation of the yale physical activity survey in chronic obstructive pulmonary disease patients'. *Archives of Bronconeumologia* 47 (11), 552-560

Donaldson, G.C., Wilkinson, T.M., Hurst, J.R., Perera, W.R. and Wedzicha, J.A. (2005) 'Exacerbations and time spent outdoors in chronic obstructive pulmonary disease'. *American Journal of Respiratory Critical Care Medicine* 171 (5), 446-452

Donaldson, G.C., Seemungal, T.A., Bhowmik, A. and Wedzicha, J.A. (2002) 'Relationship between exacerbation frequency and lung function decline in chronic obstructive pulmonary disease'. *Thorax* 57 (10), 847-852

Dowson, C., Town, I., Frampton, C. and Mulder, R.T. (2004) 'Psychopathology and illness beliefs influence COPD self-management'. *Journal of Psychosomatic Research* 56 (2004), 333-340

Effing, T., Bourbeau, J., Vercoulen, J., Apter, A., Coultas, D., Meek, P., van der Valk, P., Partridge, M., and van der Palen, J. (2012) 'Self-management Programmes for COPD: Moving Forward'. *Chronic Respiratory Disease* 9 (1), 27-35

Effing, T., Zielhuis, G., Kerstjens, H., van der Vaulk, P., and van der Palen, J. (2011) 'Community based physiotherapeutic exercise in COPD self-management: a randomised controlled trial'. *Respiratory Medicine* 105 (3), 418-426

Effing, T., Monninkhof, E.M., van der Valk, P.D., van der Palen, J., van Herwaarden, C.L., Partidge, M.R., Walters, E.H. and Zielhuis, G.A. (2007) 'Self-management education for patients with chronic obstructive pulmonary disease'. *Cochrane Database Systematic Review* (4), CD002990

Egan, C., Deering, B.M., Blake, C., Fullen, B.M., McCormack, N.M., Spruit, M.A., and Costello, R.W. (2012) 'Short term and long term effects of pulmonary rehabilitation on physical activity in COPD'. *Respiratory Meicine* 106 (12), 1671-1679

Eisner, M.D., Blanc, P.D., Yelin, E.H., Katz, P.P., Sanchez, G., Iribarren, C., and Omachi, T.A. (2010) 'Influence of anxiety on health outcomes in COPD'. *Thorax* 65 (3), 229-234

Esteban, C., Quintana, J.M., Aburto, M., Moraza, J., Egurrola, M., Perez-Izquierdo, J., Aizpiri, S., Aguirre, U., and Capelastegui, A. (2010) 'Impact of changes in physical activity on health-related quality of life among patients with COPD'. *European Respiratory Journal* 36 (2), 292-300

Evans, R.A., Singh, S.J., Collier, R., Loke, I., Steiner, M.C., and Morgan, M.D. (2010) 'Generic, symptom based, exercise rehabilitation; integrating patients with COPD and heart failure'. *Respiratory Medicine* 104 (10), 1473-1481

Ewart, C.K., Taylor, C.B., Reese, L.B., and de Busk, R.F. (1983) 'Effects of early postmyocardial infarction exercise testing on self-perception and subsequent physical activity'. *American Journal of Cardiology* 51(7),1076-80

Fan, V.S., Gaziano, J.M., Lew, R., Bourbeau, J., Adams, S.G., Leatherman, S., Thwin, S.S., Huang, G.D., Robbins, R., Sriram, P.S., Sharafkhaneh, A., Mador, M.J., Sarosi, G., Panos, R.J., Rastogi, P., Wagner, T.H., Mazzuca, S.A., Shannon, C., Colling, C., Liang, M.H., Stoller, J.K., Fiore, L., and Niewoehner, D.E. (2012) 'A comprehensive care management program to prevent chronic obstructive pulmonary disease hospitalizations: a randomized, controlled trial'. *Annals of Internal Medicine* 156 (10), 673-683

Fernandez, A.M., Pascual, J., Ferrando, C., Arnal, A., Vergara, I., and Sevila, V. (2009) 'Home-based pulmonary rehabilitation in very severe COPD: is it safe and useful?'. *Journal of Cardiopulmonary Rehabilitation and Prevention* 29 (5), 325-331

Ferrannini, E. (1988) 'The theoretical bases of indirect calorimetry: a review'. *Metabolism* 37 (3), 287-301

Ferrer, M., Alonso, J., Morera, J., Marrades, R.M., Khalaf, A., Aguar, M.C., Plaza, V., Prieto, L., and Anto, J.M. (1997) 'Chronic obstructive pulmonary disease stage and health-related quality of life. The Quality of Life of Chronic Obstructive Pulmonary Disease Study Group'. *Annals of Internal Medicine* 127 (12), 1072-1079

Fletcher, C. and Peto, R. (1977) 'The natural history of chronic airflow obstruction'. *British Medical Journal* 1 (6077), 1645-1648

Fletcher, C.M., Elmes, P.C., Fairbrain, A.S., and Wood, C.H. (1959) 'The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population'. *British Medical Journal* 2 (5147), 257-266

Food and Agriculture Organization (FAO), World Health Organisation (WHO) and United Nations University [UNU (2001)] *Human Energy Requirements: Report of a joint FAO/ WHO/ UNU Expert Consultation* [online] available from <http://www.fao.org/docrep/007/y5686e/y5686e00.htm> [12 April 2013]

Furlanetto, K.C., Bisca, G.W., Oldemburg, N.,Sant'ana, T.J., Morakami, F. K., Camillo, C.A., Cavelheri, V., Hernandes, N.A., Probst, V.S., Ramos, E.M., Brunetto, A.F., Pitta, F. (2010) 'Step counting and energy expenditure estimation in patients with chronic obstructive pulmonary disease and healthy elderly: accuracy of 2 motion sensors'. *Archives of Physical Medicine and Rehabilitation* 9 (2), 261-267

Gadoury, M.A., Schwartzman, K., Rouleau, M., Maltais, F., Julien, M., Beaupre, A., Renzi, P., Begin, R., Nault, D., and Bourbeau, J. (2005) 'Self-management reduces both short- and long-term hospitalisation in COPD'. *European Respiratory Journal* 26 (5), 853-857

Garcia-Aymerich, J., Serra, I., Gomez, F.P., Farrero, E., Balcells, E., Rodriguez, D.A., de, B.J., Gimeno, E., Donaire-Gonzalez, D., Orozco-Levi, M., Sauleda, J., Gea, J., Rodriguez-Roisin, R., Roca, J., Agusti, A.G., and Anto, J.M. (2009) 'Physical activity and clinical and functional status in COPD'. *Chest* 136 (1), 62-70

Garcia-Aymerich, J., Lange, P., Benet, M., Schnohr, P. and Anto, J.M. (2006) 'Regular physical activity reduces hospital admission and mortality in chronic obstructive pulmonary disease: a population based cohort study'. *Thorax* 61 (9), 772-778

Garcia-Aymerich, J., Felez, M.A., Escarrabill, J., Marrades, R.M., Morera, J., Elouise, R. and Anto, J.M. (2004) Physical activity and its determinants in severe chronic obstructive pulmonary disease'. *Medicine and Science in Sports and Exercise* [online] available from <http://www.sentacollege.com/wp-content/uploads/Journal_db?Physical%20Acrivity%20and%20Its%20Determinants%20in.pdf> [April 2013]

Garcia-Aymerich, J., Farrero, E., Felez, M.A., Izquierdo, J., Marrades, R.M., and Anto, J.M. (2003) 'Risk factors of readmission to hospital for a COPD exacerbation: a prospective study'. *Thorax* 58 (2), 100-105

Ghanem, M., Elaal, E.A., Mehany, M., and Tolba, K. (2010) 'Home-based pulmonary rehabilitation program: Effect on exercise tolerance and quality of life in chronic obstructive pulmonary disease patients'. *Annals of Thoracic Medicine* 5 (1), 18-25

Global Initiative for Chronic Obstructive Lung Disease GOLD (2013) *Global strategy for disgnosis, management and prevention of COPD* [online] available at <http:www.goldcopd.org/uploads/users/files/GOPLD_Report_2013_Feb20.pdf> [April 2013]

Global Initiative for Chronic Lung Disease GOLD (2011) *Global strategy for disgnosis, management and prevention of COPD* [online] available from <http://www.goldcopd.org/> [Feb 2012]

Godtfredsen, N.S., Lam, T.H., Hansel, T.T., Leon, M.E., Gray, N., Dresler, C., Burns, D.M., Prescott, E., and Vestbo, J. (2008) 'COPD-related morbidity and mortality after smoking cessation: status of the evidence'. *European Respiratory Journal* 32 (4), 844-853

Gollwitzer, P.M. (1999) 'Implementation Intentions. Strong effects of simple plans'. *American Psychologist* 54, 493-503

Griffiths, T.L., Burr, M.L., Campbell, I.A., Lewis-Jenkins, V., Mullins, J., Shiels, K., Turner-Lawlor, P.J., Payne, N., Newcombe, R.G., Ionescu, A.A., Thomas, J., and Tunbridge, J. (2000) 'Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial'. *Lancet* 355 (9201), 362-368

Guyatt, G.H., Berman, L.B., Townsend, M., Pugsley, S.O., and Chambers, L.W. (1987) 'A measure of quality of life for clinical trials in chronic lung disease'. *Thorax* 42 (10), 773-778

Hajiro, T., Nishimura, K., Tsukino, M., Ikeda, A., Oga, T., and Izumi, T. (1999) 'A comparison of the level of dyspnoea vs disease severiry in indicating the health-related quality of life of patients with COPD'. *Chest* 116 (6), 1632-1637

Hanania, N.A., Mullerova, H., Locantore, N.W., Vestbo, J., Watkins, M.L., Wouters, E.F., Rennard, S.I., and Sharafkhaneh, A. (2010) 'Determinants of Depression in the ECLIPSE COPD Cohort'. *American Journal of Respiratory and Critical Care Medicine* 183 (5), 604-11

Harris, J.A. and Benedict, F.G. (1918) 'A biometric study of human basal metabolism'. *Proceedings of the National Academy of Sciences of the United States of America* 4 (12), 370-373

Harrison, M., Fullwood, C., Bower, P., Kennedy, A., Rogers, A., and Reeves, D. (2011) 'Exploring the mechanisms of change in the chronic disease self-management programme: secondary analysis of data from a randomised controlled trial'. *Patientient Education and Counseling* [online] 85 (2), e39-e47. available from <http://www.sciencedirect.com/science/article/pii/S0738399110006348> [April 2013]

Harrison, S.L., Greening, N.J., Williams, J.E., Morgan, M.D., Steiner, M.C,. and Singh, S.J. (2012) 'Have we underestimated the efficacy of pulmonary rehabilitation in improving mood?'. *Respiratory Medi*cine 106 (6), 838-844

Hart, T.L., Swartz, A.M., Cashin, S.E., and Strath, S.J. (2011) 'How many days of monitoring predict physical activity and sedentary behaviour in older adults?'. *International Journal of Behavioral Nutrition and Physical Activity* [online] 8: 62 doi: 10.1186/1479-5868-8-62. available from <http://www.biomedicalcentral.com/content/pdf/1479-5868-8-62.pdf> [April 2013]

Haskell, W.L., Lee, I.M., Pate, R.R., Powell, K.E., Blair, S.N., Franklin, B.A., Macera, C.A., Heath, G.W., Thompson, P.D., and Bauman, A. (2007) 'Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association'. *Circulation* 116 (9), 1081-1093

Hawkins, S.Y. (2010) 'Improving glycemic control in older adults using a videophone motivational diabetes self-management intervention'. *Research and Theory for Nursing Practice* 24 (4), 217-232

Healthcare Commission (2006) *Clearing the air: a national study of chronic obstructive pulmonary disease*. London: Healthcare Commission.

Hecht, A., Ma, S., Porszasz, J., and Casaburi, R. (2009) 'Methodology for using long-term accelerometry monitoring to describe daily activity patterns in COPD'. *COPD* 6 (2), 121-129

Hernandes, N.A., Teixeira, D.C., Probst, V.S., Brunetto, A.F., Ramos, E.M., and Pitta, F. (2009) 'Profile of the level of physical activity in the daily lives of patients with COPD in Brazil'. *Journal of Brasileiro Pneumologia* 35 (10), 949-956

Hettema, J., Steele, J. and Miller, W.R. (2005) 'Motivational interviewing'. *Annual Review Clinical Psychology* 1, 91-111

Hicks, J. and Allen, G. (1999) *A century of change: trends in UK statistics since 1900.* Social and General Statistics Section: House of Commons Library

Hill, K., Dolmage, T.E., Woon, L., Coutts, D., Goldstein, R., and Brooks D. (2012) 'Defining the relationship between average daily energy expenditure and field-based walking tests and aerobic reserve in COPD'. *Chest* 141 (2), 406-412

Hill, K., Dolmage, T.E., Woon, L., Goldstein, R., and Brooks, D. (2010a) 'Measurement properties of the SenseWear armband in adults with chronic obstructive pulmonary disease'. *Thorax* 65 (6), 486-491

Hill, K., Mangovski-Alzamora, S., Blouin, M., Guyatt, G., Heels-Ansdell, D., Bragaglia, P., Tamari, I., Jones, K., and Goldstein, R. (2010b) 'Disease-specific education in the primary care setting increases the knowledge of people with chronic obstructive pulmonary disease: a randomized controlled trial'. *Patientient Education and Counseling* 81 (1), 14-18

Hollis, S. and Campbell, F. (1999) 'What is meant by intention to treat analysis? Survey of published randomised controlled trials'. *British Medical Journal* 319 (7211), 670-674

Holman, H. and Lorig, K. (2004) 'Patient self-management: a key to effectiveness and efficiency in care of chronic disease'. *Public Health Reports* 119 (3), 239-243

Hoogendoorn, M., Feenstra, T.L., Hoogenveen, R.T., and Rutten-van Molken, M.P. (2010) 'Long-term effectiveness and cost-effectiveness of smoking cessation interventions in patients with COPD'. *Thorax* 65 (8), 711-718

Hopkinson, N.S. and Polkey, M.I. (2010) 'Does physical inactivity cause chronic obstructive pulmonary disease?'. *Clinical Science (London)* 118 (9), 565-572

Hyland, M.E., Jones, R.C., and Hanney, K.E. (2006) 'The Lung Information Needs Questionnaire: Development, preliminary validation and findings'. *Respiratory Medicine* 100 (10), 1807-1816

Jaeschke, R., Singer, J., and Guyatt, G.H. (1989) 'Measurement of health status. Ascertaining the minimal clinically important difference'. *Controlled Clinical Trials* 10 (4), 407-415

Janssen, D.J., Spruit, M.A., Leue, C., Gijsen, C., Hameleers, H., Schols, J.M., and Wouters, E.F. (2010) 'Symptoms of anxiety and depression in people entering pulmonary rehabilitation'. *Chronic Respiratory Disease* 7 (3), 147-157

Jones, P.W., Harding, G., Berry, P., Wiklund, I., Chen, W.H., and Kline Leidy, N. (2009) 'Development and first validation of the COPD assessment test'. *European Respiratory Journal* 34 (3), 648-54

Jones, P.W., Quirk, F.H., and Baveystock, C.M. (1991) 'The St George's Respiratory Questionnaire'. *Respiratory Medicine* 85 Suppl B, 25-31

Jones, R.C., Wang, X., Harding, S., Bott, J., and Hyland, M. (2008) 'Educational impact of pulmonary rehabilitation: Lung Information Needs Questionnaire'. *Respiratory Medicine* 102 (10), 1439-1445

Kanner, R.E., Connett, J.E., Williams, D.E., and Buist, S. 'Effects of a randomized assignment to a smoking cessation intervention and changes in smoking habits on respiratory symptoms in smokers with early chronic obstructive pulmonary disease: the lung health study'. T*he American Journal of Medicine* 106 (4), 410-416

Kaplan, R.M., Atkins, C.J., and Reinsch, S. (1984) 'Specific efficacy expectations mediate exercise compliance in patients with COPD'. *Health Psychology* 3 (3), 223-242

Katz, P., Chen, H., Omachi, T.A., Gregorich, S.E., Julian, L., Cisternas, M., Balmes, J., and Blanc, P.D. (2011) 'The role of physical inactivity in increasing disability among older adults with obstructive airway disease'. *Journal of Cardiopulmonary Rehabilitation and Prevention* 31 (3), 193-197

Kennedy, A., Reeves, D., Bower, P., Lee, V., Middleton, E., Richardson, G., Gardener, C., Gately, C., and Rogers, A. (2007) 'The effectiveness and cost effectiveness of a national lay-led self care support programme for patients with long-term conditions: a pragmatic randomised controlled trial'. *Journal of Epidemiology Community Health* 61, 254-261

Khdour, M.R., Agus, A.M., Kidney, J.C., Smyth, B.M., Elnay, J.C., and Crealey, G.E. (2011) 'Cost-utility analysis of a pharmacy-led self-management programme for patients with COPD'. *International Journal of Clinical Pharmacy* 33 (4), 665-673

Khdour, M.R., Kidney, J.C., Smyth, B.M., and McElnay, J.C. (2009) 'Clinical pharmacy-led disease and medicine management programme for patients with COPD'. *British Journal of Clinical Pharmacology* 68 (4), 588-598

Khunti, K., Gray, L.J., Skinner, T., Carey, M.E., Realf, K., Dallosso, H., Fisher, H., Campbell, M., Heller, S. and Davies, M.J. (2012) 'Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care'. *British Medical Journal* [online] 344, e2333. available from <http://www.bmj.com/content/344/bmj.e2333> [April 2013]

Kim, H.F., Kunik, M.E., Molinari, V.A., Hillman, S.L., Lalani, S., Orengo, C.A., Petersen, N.J., Nahas, Z., and Goodnight-White, S. (2000). 'Functional impairment in COPD patients: the impact of anxiety and depression'. *Psychosomatics* 41 (6), 465-471

Ko, S.H., Park, S.A., Cho, J.H., Ko, S.H., Shin, K.M., Lee, S.H., Song, K.H., Park, Y.M., and Ahn, Y.B. (2012) 'Influence of the duration of diabetes on the outcome of a diabetes self-management education program'. *Diabetes and Metabolism Journal* 36 (3), 222-229

Kohl, H.W., III, Craig, C.L., Lambert, E.V., Inoue, S., Alkandari, J.R., Leetongin, G., and Kahlmeier, S. (2012) 'The pandemic of physical inactivity: global action for public health'. *Lancet* 380 (9838), 294-305

Lacasse, Y., Goldstein, R., Lasserson, T.J., and Martin, S. (2006) 'Pulmonary rehabilitation for chronic obstructive pulmonary disease'. *Cochrane Database Systematic Review* (4) CD003793

Landsberger, H. (1958) *Hawthorne Revistited.* Ithaca: Cornell University

Langer, D., Gosselink, R., Sena, R., Burtin, C., Decramer, M., and Troosters, T. (2009) 'Validation of two activity monitors in patients with COPD'. *Thorax* 64 (7), 641-642

Le Masurier, G.C., Sidman, C.L., and Corbin, C.B. (2003) 'Accumulating 10,000 steps: does this meet current physical activity guidelines?'. *Research Qqarterly for Exercise and Sport* 74 (4), 389-394

Lee, I.M., Shiroma, E.J., Lobelo, F., Puska, P., Blair, S.N., and Katzmarzyk, P.T. (2012) 'Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy'. *Lancet* 380 (9838), 219-229

Lee, Y.J., Ellenberg, J.H., Hirtz, D.G., and Nelson, K.B. (1991) 'Analysis of clinical trials by treatment actually received: is it really an option?'. *Statistics in Medicine* 10 (10), 1595-1605

Linden, A., Butterworth, S.W., and Prochaska, J.O. (2010) 'Motivational interviewing-based health coaching as a chronic care intervention'. *Journal of Evaluation in Clinical Practice* 16 (1), 166-174

Lorig, K.R. and Holman, H. (2003) 'Self-management education: history, definition, outcomes, and mechanisms'. *Annals of Behavioral Medicine* 26 (1), 1-7

Mador, M.J., Patel, A.N., and Nadler, J. (2011) 'Effects of pulmonary rehabilitation on activity levels in patients with chronic obstructive pulmonary disease'. *Journal of Cardiopulmonary Rehabilitation and Prevention* 31 (1), 52-59

Maltais, F., Bourbeau, J., Shapiro, S., Lacasse, Y., Perrault, H., Baltzan, M., Hernandez, P., Rouleau, M., Julien, M., Parenteau, S., Paradis, B., Levy, R.D., Camp, P., Lecours, R., Audet, R., Hutton, B., Penrod, J.R., Picard, D., Bernard, S., and Chronic, O. (2008) 'Effects of home-based pulmonary rehabilitation in patients with chronic obstructive pulmonary disease: a randomized trial'. *Annals of Internal Medicine* 149 (12), 869-878

Mannino, D.M. and Buist, A.S. (2007) 'Global burden of COPD: risk factors, prevalence, and future trends'. *Lancet* 370 (9589), 765-773

Martin, S.B., Morrow, J.R., Jr., Jackson, A.W., and Dunn, A.L. (2000) 'Variables related to meeting the CDC/ACSM physical activity guidelines'. *Medicine and Science in Sports and Exercise* 32 (12), 2087-2092

Matthews, C.E., Ainsworth, B.E., Thompson, R.W., and Bassett, D.R., Jr. (2002) 'Sources of variance in daily physical activity levels as measured by an accelerometer'. *Medicine and Science in Sports and Exercise* 34 (8), 1376-1381

Maurer, J., Rebbapragada, V., Borson, S., Goldstein, R., Kunik, M., Yohannes, A., and Hanania, N. (2008) ' Anxiety and depression in COPD. Current understanding, unanswered questions, and research needs'. *Chest* 134 (4), 43S-56S

McCambridge, J., de Bruin, M., and Witton, J. (2012) 'The effects of demand characteristics on research participant behaviours in non-laboratory settings: a systematic review'. *PLoS One* [online] 7 (6), e39116. available from <111.plosone.org/article/info:doi10.1371/journal.pone.0039116 [April 2013]

McCambridge, J., Butor-Bhavsar, K., Witton, J., and Elbourne, D. (2011) 'Can research assessments themselves cause bias in behaviour change trials? A systematic review of evidence from solomon 4-group studies'. *PLoS One* [online] 6 (10) e25223. available from

<www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0025223> [April 2013]

McGeoch, G.R.B., Willsman, K.J., Dowson, C.A., Town, G.I., Frampton, C.M., McCartin, F.J., Cook, J.M., and Epton, M.J. (2006) 'Self-management plans in the primary care of patients with chronic obstructive pulmonary disease'. *Respirology* 11 (5), 611-618

McGlone, S., Venn, A., Walters, E.H., and Wood-Baker, R. (2006) 'Physical activity, spirometry and quality of life in chronic obstructive pulmonary disease'. *Journal of Chronic Obstructive Pulmonary Disease* 3 (2), 83-88

Medical Research Council (2008) *Complex Interventions Guideance* [online] available from <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871> [April 2013]

Meijer, E.P., Goris, A.H., Wouters, L., and Westerterp, K.R. (2001) 'Physical inactivity as a determinant of the physical activity level in the elderly'. *International Journal of Obesity Related Metabolic Disorders* 25 (7), 935-939

Mendes, J.C., Studart, F.S., Malosa, L.M., Negrinho, A.C., Hirata, R.P., Costa, D., Donner, C.F., and de Oliveira, L.V.F. (2010) 'Outpatient vs. home-based pulmonary rehabilitation in COPD: A randomized controlled trial'. *Multidisciplinary Respiratory Medicine* 5 (6), 401-408

Meseguer, C.M., Galan, I., Herruzo, R., Zorrilla, B., and Rodriguez-Artalejo, F. (2009) 'Leisure-time physical activity in a southern European mediterranean country: adherence to recommendations and determining factors'. *Revista Espanola de Cardiologia* 62 (10), 1125-1133

Miller, N.E. and Dollard, J. (1941) *Social Learning and Limitation.* New Haven: Yale University Press

Miller, W. (1983) 'Motivational Interviewing with Problem drinkers'. *Behavioural Psychotherapy* 11 (2), 147-172

Miller, W. and Rollnick, S. (2002) *Motivational Interviewing: preparing People for Change.* 2nd edn. New York: Guilford Press

Monninkhof, E., van der Aa, M., van der Vaulk, P., van der Palen, J., Zielhuis, G., Koning, K., and Pieterse, M. (2004a) 'A qualitative evaluation of a comprehensive self-management programme for COPD patients: effectiveness from the patients' perspectice'. *Patient Education and Counseling* 55 (2), 177-184

Monninkhof, E., van der Vaulk, P., V, Schermer, T., van der Palen, J., van, Herwaarden, C., and Zielhuis, G. (2004b) 'Economic evaluation of a comprehensive self-management programme in patients with moderate to severe chronic obstructive pulmonary disease'. *Chronic Respiratory Disease* 1 (1), 7-16

Monninkhof, E., van der Vaulk, P., van der Palen, J., van Herwaarden, C., and Zielhuis, G. (2003) 'Effects of a comprehensive self-management programme in patients with chronic obstructive pulmonary disease'. *European Respiratory Journal* 22 (5), 815-820

Moore, J., Fiddler, H., Seymour, J., Grant, A., Jolley, C., Johnson, L., and Moxham, J. (2009) 'Effect of a home exercise video programme in patients with chronic obstructive pulmonary disease'. *Journal of Rehabilitation Medicine* 41 (3), 195-200

Morris, J.N. and Crawford, M.D. (1958) 'Coronary heart disease and physical activity of work; evidence of a national necropsy survey'. *British Medical Journal* 2 (5111), 1485-1496

Moy, M.L., Reilly, J.J., Ries, A.L., Mosenifar, Z., Kaplan, R.M., Lew, R., and Garshick, E. (2009) 'Multivariate models of determinants of health-related quality of life in severe chronic obstructive pulmonary disease'. *Journal of Rehabilitation Research and Development* 46 (5), 643-654

National Institute for Clinical Excellence (2010) *Clinical Guideline 101: Chronic obstructive pulmonary disease - Management of chronic obstructive pulmonary disease in adults in primary and secondary care* [online] available from http://guidance.nice.org.uk/CG101/NICEGuidance/pdf/English [April 2013]

Nelson, M.E., Rejeski, W.J., Blair, S.N., Duncan, P.W., Judge, J.O., King, A.C., Macera, C.A., and Castaneda-Sceppa, C. (2007) 'Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association'. *Circulation* 116 (9), 1094-1105

Ng, L.W.C., Mackney, J., Jenkins, S., and Hill, K. (2012) 'Does exercise training change physical activity in people with COPD? A systematic review and meta-analysis'. *Chronic Respiratory Disease* 9 (1), 18-26

Nguyen, H.Q., Burr, R.L., Gill, D.P., and Coleman, K. (2011) 'Validation of the StepWatch device for measurement of free-living ambulatory activity in patients with chronic obstructive pulmonary disease'. *Journal of Nursing Measurement* 19 (2), 76-90

NHS Improvement Lung (2013) *COPD Value Pyramid* [online] available from<http://www.improvement.nhs.uk/lung/NationalImprovementProjects/AccurateDiagnosis/SuspectedCOPD/Therapy.aspx> [April 2013]

Nici, L., Donner, C., Wouters, E., ZuWallack, R., Ambrosino, N., Bourbeau, J., Carone, M., Celli, B., Engelen, M., Fahy, B., Garvey, C., Goldstein, R., Gosselink, R., Lareau, S., MacIntyre, N., Maltais, F., Morgan, M., O'Donnell, D., Prefault, C., Reardon, J., Rochester, C., Schols, A., Singh, S., and Troosters, T. (2006) 'American Thoracic Society/European Respiratory Society statement on pulmonary rehabilitation'. *American Journal of Respiratory and Critical Care Medicine* 173 (12), 1390-1413

Ninot, G., Moullec, G., Picot, M.C., Jaussent, A., Hayot, M., Desplan, M., Brun, J.F., Mercier, J., and Prefaut, C. (2011) 'Cost-saving effect of supervised exercise associated to COPD self-management education program'. *Respiratory Medicine* 105 (3), 377-385

O'Connor, P.J,. Petruzzello, S.J., Kubitz, K.A., and Robinson, T.L. (1995) 'Anxiety responses to maximal exercise testing'. *British Journal of Sports Medicine 29* (2), 97-102

O'Donnell, D.E., Revill, S.M., and Webb, K.A. (2001) 'Dynamic hyperinflation and exercise intolerance in chronic obstructive pulmonary disease'. *American Journal of Respiratory and Critical Care Medicine* 164 (5), 770-777

Office for National Statistics (2011) *Deaths registered in England and Wales in 2010, by cause* [online] available from <http://www.ons.gov.uk/ons/dcp171778_239518.pdf> [April 2013]

Omachi, T.A., Katz, P.P., Yelin, E.H., Gregorich, S.E., Iribarren, C., Blanc, P.D., and Eisner, M.D. (2009) 'Depression and health-related quality of life in chronic obstructive pulmonary disease'. *American Journal of Medicine* 122 (8), 778-15

Palange, P., Ward, S.A., Carlsen, K.H., Casaburi, R., Gallagher, C.G., Gosselink, R., O'Donnell, D.E., Puente-Maestu, L., Schols, A.M., Singh, S., and Whipp, B.J. (2007) 'Recommendations on the use of exercise testing in clinical practice'. *European Respiratory Journal* 29 (1), 185-209

Paterson, B., Thorne, S., and Russell, C. (2002) 'Disease-specific influences on meaning and significance in self-care decision-making in chronic illness'. *Canadian Journal of Nursing Research* 34 (3), 61-74

Paterson, B. and Thorne, S. (2000) 'Expert decision making in relation to unanticipated blood glucose levels'. *Research in Nursing Health* 23 (2), 147-157

Pauwels, R.A. and Rabe, K.F. (2004) 'Burden and clinical features of chronic obstructive pulmonary disease (COPD)'. *Lancet* 364 (9434), 613-620

Pepin, V., Laviolette, L., Brouillard, C., Sewell, L., Singh, S.J., Revill, S.M., Lacasse, Y., and Maltais, F. (2011) 'Significance of changes in endurance shuttle walking performance'. *Thorax* 66 (2), 115-120

Peterson, S., Taube, K., Lehmann, K., van den Bergh, O., and Leupoldt, A. (2012) ' Social comparison and anxious mood in pulmonary rehabilitation: The role of cognitive focus'. *British Journal of Health Psychology* 17, 463-476

Pitta, F., Breyer, M.K., Hernandes, N.A., Teixeira, D., Sant'anna, T.J., Fontana, A.D., Probst, V.S., Brunetto, A.F., Spruit, M.A., Wouters, E.F., Burghuber, O.C., and Hartl, S. (2009) 'Comparison of daily physical activity between COPD patients from Central Europe and South America'. *Respiratory Medicine* 103 (3), 421-426

Pitta, F., Troosters, T., Probst, V.S., Langer, D., Decramer, M., and Gosselink, R. (2008) 'Are patients with COPD more active after pulmonary rehabilitation?'. *Chest* 134 (2), 273-280

Pitta, F., Troosters, T., Probst, V.S., Spruit, M.A., Decramer, M., and Gosselink, R. (2006) 'Physical activity and hospitalization for exacerbation of COPD'. *Chest* 129 (3), 536-544

Pitta, F., Troosters, T., Spruit, M.A., Decramer, M., and Gosselink, R. (2005a) 'Activity monitoring for assessment of physical activities in daily life in patients with chronic obstructive pulmonary disease'. *Archives of Physical Medicine and Rehabilitation* 86 (10), 1979-1985

Pitta, F., Troosters, T., Spruit, M.A., Probst, V.S., Decramer, M., and Gosselink, R. (2005b) 'Characteristics of physical activities in daily life in chronic obstructive pulmonary disease'. *America Journal of Respiratory and Critical Care Medicine* 171 (9), 972-977

Prochaska, J.O. and DiClemente, C.C. (1983) 'Stages and processes of self-change of smoking: Toward an integrative model of change'. *Journal of Consulting and Clinical Psychology* 5 (3), 390-395

Puhan, M.A., Frey, M., Buchi, S., and Schunemann, H.J. (2008) 'The minimal important difference of the hospital anxiety and depression scale in patients with chronic obstructive pulmonary disease'. *Health Quality of Life Outcomes* 6: 46 [online] available from <http://www.hqlo.com/content/6/1/46> [April 2013]

Redman, B.K. (2004) *Patient Self-management of Chronic Disease.* London: Jones and Bartlett

Revill, S.M., Morgan, M.D., Singh, S.J., Williams, J., and Hardman, A.E. (1999) 'The endurance shuttle walk: a new field test for the assessment of endurance capacity in chronic obstructive pulmonary disease'. *Thorax* 54 (3), 213-222

Rice, K.L., Dewan, N., Bloomfield, H.E., Grill, J., Schult, T.M., Nelson, D.B., Kumari, S., Thomas, M., Geist, L.J., Beaner, C., Caldwell, M., and Niewoehner, D.E. (2010) 'Disease management program for chronic obstructive pulmonary disease: a randomized controlled trial'. *American Journal of Respiratroy and Critical Care Medicine* 182 (7), 890-896

Rickheim, P.L., Weaver, T.W., Flader, J.L., and Kendall, D.M. (2002) 'Assessment of group versus individual diabetes education: a randomized study'. *Diabetes Care* 25 (2), 269-274

Ries, A.L., Bauldoff, G.S., Carlin, B.W., Casaburi, R., Emery, C.F., Mahler, D.A., Make, B., Rochester, C.L., Zuwallack, R., and Herrerias C. (2007) 'Pulmonary Rehabilitation: Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines'. *Chest* 131 (5 Suppl), 4S-42S

Rogers, R.W. (1975) 'A protection motivation theory of fear appeals and attitude change'. *Journal of Psychology* 91, 93-114

Rosenstock, I.M. (1966) 'Why people use health services'. *Milbank Memorial Fund Qquarterly* 44 (3), Suppl-127

Roth, M. (2008) 'Pathogenesis of COPD. Part III. Inflammation in COPD'. *International Journal of Tuberculosis and Lung Disease* 12 (4), 375-380

Rubak, S., Sandbaek, A., Lauritzen, T., Borch-Johnsen, K., and Christensen, B. (2009) ' General practitioners trained in motivational interviewing can positively affect the attitude to behaviour change in people with type 2 diabetes'. *Scandinavian Journal of Primary Healthcare* 27 (3), 172-179

Rubak, S., Sandbaek, A., Lauritzen, T., and Christensen, B. (2005) 'Motivational interviewing: a systematic review and meta-analysis'. *British Journal of General Practice* 55 (513), 305-312

Rydwik, E., Welmer, A.K., Kareholt, I., Angleman, S., Fratiglioni, L., and Wang, H.X. (2012) 'Adherence to physical exercise recommendations in people over 65--The SNAC-Kungsholmen study'. *European Journal of Public Health* [online] available from <http://eurpub.oxfordjournals.org/content/early/2012/10/31/eutpub.cks150> [April 2013]

Sallis, J.F., Haskell, W.L., Wood, P.D., Fortmann, S.P., Rogers, T., Blair, S.N., and Paffenbarger, R.S., Jr. (1985) 'Physical activity assessment methodology in the Five-City Project'. *American Journal of Epidemiology* 121 (1), 91-106

Sandland, C.J., Singh, S.J., Curcio, A., Jones, P.M., and Morgan, M.D. (2005) 'A profile of daily activity in chronic obstructive pulmonary disease'. *Journal of Cardiopulmonary Rehabilitation and Prevention* 25 (3), 181-183

Scanlon, P.D., Connett, J.E., Waller, L.A., Altose, M.D., Bailey, W.C., and Buist, A.S. (2000) 'Smoking cessation and lung function in mild-to-moderate chronic obstructive pulmonary disease. The Lung Health Study'. *American Journal of Respiratory and Critical Care Medicine* 161 (2 Pt 1), 381-390

Schlenk, E.A., Erlen, J.A., Dunbar-Jacob, J., McDowell, J., Engberg, S., Sereika, S.M., Rohay, J.M., and Bernier, M.J. (1998) 'Health-related quality of life in chronic disorders: a comparison across studies using the MOS SF-36'. *Quality of Life Research* 7 (1), 57-65

Schreurs, K.M., Colland, V.T., Kuijer, R.G., de Ridder, D.T., and van Elderen, T. (2003) 'Development, content, and process evaluation of a short self-management intervention in patients with chronic diseases requiring self-care behaviours'. *Patientient Education and Counseling* 51 (2), 133-141

Seamark, D.A., Blake, S.D., Seamark, C.J., and Halpin, D.M. (2004) 'Living with severe chronic obstructive pulmonary disease (COPD): perceptions of patients and their carers. An interpretative phenomenological analysis'. *Palliative Medicine* 18 (7), 619-625

Sewell, L., Singh, S.J., Williams, J.E., and Morgan, M.D. (2010) 'Seasonal variations affect physical activity and pulmonary rehabilitation outcomes'. *Journal of Cardiopulmonary Rehabilitation and Prevention* 30 (5), 329-333

Sewell, L., Singh, S.J., Williams, J.E., Collier, R., and Morgan, M.D. (2006) 'How long should outpatient pulmonary rehabilitation be? A randomised controlled trial of 4 weeks versus 7 weeks'. *Thorax* 61 (9), 767-771

Sewell, L., Singh, S.J., Williams, J.E., Collier, R., and Morgan, M.D. (2005) 'Can individualized rehabilitation improve functional independence in elderly patients with COPD?'. *Chest* 128 (3), 1194-1200

Simpson, A.C., Young, J., Donahue, M., and Rocker, G. (2010) 'A day at a time: caregiving on the edge in advanced COPD'. *International Journal of Chronic Obstructive Pulmonary Disease* 5, 141-151

Singh, S.J., Morgan, M.D., Hardman, A.E., Rowe, C., and Bardsley, P.A. (1994) 'Comparison of oxygen uptake during a conventional treadmill test and the shuttle walking test in chronic airflow limitation'. *European Respiratory Journal* 7 (11), 2016-2020

Singh, S.J., Morgan, M.D., Scott, S., Walters, D., and Hardman, A.E. (1992) 'Development of a shuttle walking test of disability in patients with chronic airways obstruction'. *Thorax* 47 (12), 1019-1024

Soler-Cataluna, J.J., Martinez-Garcia, M.A., Roman, S.P., Salcedo, E., Navarro, M., and Ochando, R. (2005) 'Severe acute exacerbations and mortality in patients with chronic obstructive pulmonary disease'. *Thorax* 60 (11), 925-931

Spence, A., Hasson, F., Waldron, M., Kernohan, G., McLaughlin, D., Cochrane, B., and Watson, B. (2008) 'Active carers: living with chronic obstructive pulmonary disease'. *International Journal of Palliative Nursing* 14 (8), 368-372

Spencer, S., Calverley, P.M., Sherwood, B.P., and Jones, P.W. (2001) 'Health status deterioration in patients with chronic obstructive pulmonary disease'. *American Journal of Respiratory and Critical Care Medicine* 163 (1), 122-128

Spruit, M.A., Pennings, H.J., Janssen, P.P., Does, J.D., Scroyen, S., Akkermans, M.A., Mostert, R., and Wouters, E.F. (2007) 'Extra-pulmonary features in COPD patients entering rehabilitation after stratification for MRC dyspnea grade'. *Respiratory Medicine* 101 (12), 2454-2463

Spruit, M.A., Gosselink, R., Troosters, T., De Paepe, K., and Decramer, M. (2002) 'Resistance versus endurance training in patients with COPD and peripheral muscle weakness'. *European Respiratory Journal* 19 (6), 1072-1078

Stang, P., Lydick, E., Silberman, C., Kempel, A., and Keating, E.T. (2000) 'The prevalence of COPD: using smoking rates to estimate disease frequency in the general population'. *Chest* 117 (5 Suppl 2), 354S-359S

Steele, B.G., Holt, L., Belza, B., Ferris, S., Lakshminaryan, S., and Buchner, D.M. (2000) 'Quantitating physical activity in COPD using a triaxial accelerometer'. *Chest* 117 (5), 1359-1367

Strecher, V.J., DeVellis, B.M., Becker, M.H., and Rosenstock, I.M. (1986) 'The role of self-efficacy in achieving health behavior change'. *Health Education Qquarterly* 13 (1), 73-92

Suissa, S., Dell'Aniello, S., and Ernst, P. (2012) 'Long-term natural history of chronic obstructive pulmonary disease: severe exacerbations and mortality'. *Thorax* 67 (11), 957-963

Sutherland, E.R. and Martin, R.J. (2003) 'Airway inflammation in chronic obstructive pulmonary disease: comparisons with asthma'. *Journal of Allergy and Clinical Immunology* 112 (5), 819-827

Tang, T.S., Funnell, M.M., Noorulla, S., Oh, M., and Brown, M.B. (2012a) 'Sustaining short-term improvements over the long-term: results from a 2-year diabetes self-management support (DSMS) intervention'. *Diabetes Research and Clinical Practice* 95 (1), 85-92

Tang, T.S., Funnell, M.M., and Oh, M. (2012b) 'Lasting effects of a 2-year diabetes self-management support intervention: outcomes at 1-year follow-up'. *Prevention of Chronic Disease* 9 [online] E109. available from <http://www.cdc.gov/pcd/issues/2012/11_0313.htm> [April 2013]

Taylor, C.B., Coffey, T., Berra, K., Iaffaldano, R., Casey, K., and Haskell, W.L. (1984) 'Seven-day activity and self-report compared to a direct measure of physical activity'. *American Journal of Epidemiology* 120 (6), 818-824

The Royal College of Physicians, British Thoracic Society and British Lung Foundation (2008) *Report of The National Chronic Obstructive Pulmonary Disease Audit 2008: Resources and Organisation of care in Acute NHS units across the UK* [online] available from <http://www.rcplondon.ac.uk/sites/default/files/report-of-the-national-copd-audit-2008-resouces-and-organisation-of-care-in-acute-nhs-units-across-the-uk.pdf> [April 2013]

The Royal College of Physicians and the BritishThoracic Society (2004) *Report of the 2003 National COPD Audit* [online] available from <http://rcplondon.ac.uk/sites/default/files/ncrop-national-copd-audit-2003-report.pdf> [April 2013]

Thorne, S., Paterson, B., and Russell, C. (2003) 'The structure of everyday self-care decision making in chronic illness'. *Qualitative Health Research* 13 (10), 1337-1352

Troosters, T., Sciurba, F., Battaglia, S., Langer, D., Valluri, S.R., Martino, L., Benzo, R., Andre, D., Weisman, I., and Decramer, M. (2010) 'Physical inactivity in patients with COPD, a controlled multi-center pilot-study'. *Respiratory Medicine* 104 (7), 1005-1011

Troosters, T., Gosselink, R., and Decramer, M. (2000) 'Short- and long-term effects of outpatient rehabilitation in patients with chronic obstructive pulmonary disease: a randomized trial'. *American Journal of Medicine* 109 (3), 207-212

Tudor-Locke, C., Burkett, L., Reis, J.P., Ainsworth, B.E., Macera, C.A., and Wilson, D.K. (2005) 'How many days of pedometer monitoring predict weekly physical activity in adults?'. *Preventive Medicine* 40 (3), 293-298

Turner, L.J., Houchen, L., Williams, J., and Singh, S.J. (2012) 'Reliability of pedometers to measure step counts in patients with chronic respiratory disease'. *Journal of Cardiopulmonary Rehabilitation and Prevention* 32 (5), 284-291

UK National Statistics (2007) *General Household Survey, 2007 Report* [online] available from <http://www.ons.gov.uk/ons/rel/ghs/general-household-survey/2007-report/index.html> [April 2013]

Vaes, A.W., Wouters, E.F., Franssen, F.M., Uszko-Lencer, N.H., Stakenborg, K.H., Westra, M., Meijer, K., Schols, A.M., Janssen, P.P., and Spruit, M.A. (2011) 'Task-related oxygen uptake during domestic activities of daily life in patients with COPD and healthy elderly subjects'. *Chest* 140 (4), 970-979

van der Molen, T. (2010) 'Co-morbidities o COPD in primary care: frequency, relation to COPD, and treatment consuquences' *Primary Care Respiratory Journal 19* (4), 326-334

van Remoortel, H., Raste, Y., Louvaris, Z., Giavedoni, S., Burtin, C., Langer, D., Wilson, F., Rabinovich, R., Vogiatzis, I., Hopkinson, N.S., and Troosters, T. (2012) 'Validity of six activity monitors in chronic obstructive pulmonary disease: a comparison with indirect calorimetry'. *PLoS One* [online] 7 (6) e39198. available from <http:www.plosone.org/article/info:doi/10.1371/journal.pone.0039198> [April 2013]

van Rutten, M.M., Roos, B., and van Noord, J.A. (1999) 'An empirical comparison of the St George's Respiratory Questionnaire (SGRQ) and the Chronic Respiratory Disease Questionnaire (CRQ) in a clinical trial setting'. *Thorax* 54 (11), 995-1003

van Sluijs, E.M., van Poppel, M.N., Twisk, J.W., and van Mechelen, W. (2006) 'Physical activity measurements affected participants' behavior in a randomized controlled trial'. *Journal of Clinical Epidemiology* 59 (4), 404-411

Vincent, E., Sewell, L., Wagg, K., Deacon, S., Williams, J., and Singh, S. (2011) 'Measuring a change in self-efficacy following Pulmonary Rehabilitation: An evaluation of the PRAISE tool'. *Chest* 140 (6), 1534-1539

Vitorasso, R., Camillo, C.A., Cavalheri, V., Aparecida, H.N., Cortez, V.A., Sant'anna, T., Ferreira, M.F., Ramos, E.M., and Pitta, F. (2012) 'Is walking in daily life a moderate intensity activity in patients with chronic obstructive

pulmonary disease?'. *European Journal of Physical Rehabilitation Medicine* 48 (4), 587-592

Voll-Aanerud, M., Eagan, T.M., Wentzel-Larsen, T., Gulsvik, A., and Bakke, P.S. (2008) 'Respiratory symptoms, COPD severity, and health related quality of life in a general population sample'. *Respiratory Medicine* 102 (3), 399-406

Wagg, K. (2012) 'Unravelling self-management for COPD: what next?'. *Chronic Respiratory Disease* 9 (1), 5-7

Wagner, E.H. (1998) 'Chronic disease management: what will it take to improve care for chronic illness?'. *Effective Clinical Practice* 1 (1), 2-4

Wagner, E.H. (1997) 'Managed care and chronic illness: health services research needs'. *Health Services Research* 32 (5), 702-714

Walters, J.A., Cameron-Tucker, H., Courtney-Pratt, H., Nelson, M., Robinson, A., Scott, J., Turner, P., Walters, E.H., and Wood-Baker, R. (2012) 'Supporting health behaviour change in chronic obstructive pulmonary disease with telephone health-mentoring: insights from a qualitative study'. *Biomed Central Family Practice* [online] 13: 55. available from <http://www.biomedcentral.com/1471-2296/13/55> [June 2012]

Walters, J.A., Turnock, A.C., Walters, E.H., and Wood-Baker, R. (2010) 'Action plans with limited patient education only for exacerbations of chronic obstructive pulmonary disease'. *Cochrane Database Systematic Review* (5) CD005074

Waschki, B., Spruit, M.A., Watz, H., Albert, P.S., Shrikrishna, D., Groenen, M., Smith, C., Man, W.D., Tal-Singer, R., Edwards, L.D., Calverley, P.M., Magnussen, H., Polkey, M.I., and Wouters, E.F. (2012) 'Physical activity monitoring in COPD: compliance and associations with clinical characteristics in a multicenter study'. *Respiratory Medicine* 106 (4), 522-530

Waschki, B., Kirsten, A., Holz, O., Muller, K.C., Meyer, T., Watz, H., and Magnussen, H. (2011) 'Physical activity is the strongest predictor of all-cause mortality in patients with COPD: a prospective cohort study'. *Chest* 140 (2), 331-342

Watson, P.B., Town, G.I., Holbrook, N., Dwan, C., Toop, L.J., and Drennan, C.J. (1997) 'Evaluation of a self-management plan for chronic obstructive pulmonary disease'. *European Respiratory Journal* 10 (6), 1267-1271

Watz, H., Waschki, B., Meyer, T., and Magnussen, H. (2009) 'Physical activity in patients with COPD'. *European Respiratory Journal* 33 (2), 262-272

White, R., Walker, P., Roberts, S., Kalisky, S., and White, P. (2006) 'Bristol COPD Knowledge Questionnaire (BCKQ): testing what we teach patients about COPD'. *Chronic Respiratory Disease* 3 (3), 123-131

Wigal, J.K., Creer, T.L., and Kotses, H. (1991) 'The COPD Self-Efficacy Scale'. *Chest* 99 (5), 1193-1196

Wilke, S., Janssen, D.J., Wouters, E.F., Schols, J.M., Franssen, F.M., and Spruit, M.A. (2012) 'Correlations between disease-specific and generic health status questionnaires in patients with advanced COPD: a one-year observational study'. *Health and Quality of Life Outcomes* [online] 10, 98. available from < http://www.hqlo.com/content/10/1/98> [April 2013]

Willemse, B.W., ten Hacken, N.H., Rutgers, B., Lesman-Leegte, I.G., Postma, D.S., and Timens, W. (2005) 'Effect of 1-year smoking cessation on airway inflammation in COPD and asymptomatic smokers'. *European Respiratory Journal* 26 (5), 835-845

Williams, J.E., Singh, S.J., Sewell, L., and Morgan, M.D. (2003) 'Health status measurement: sensitivity of the self-reported Chronic Respiratory Questionnaire (CRQ-SR) in pulmonary rehabilitation'. *Thorax* 58 (6), 515-518

Williams, J.E., Singh, S.J., Sewell, L., Guyatt, G.H., and Morgan, M.D. (2001) 'Development of a self-reported Chronic Respiratory Questionnaire (CRQ-SR)'. *Thorax* 56 (12), 954-959

Wilsom, P. M., Kendall, S., and Brooks, F. (2007) 'The expert patients programme: a paradox of patient empowerment and medical dominance'. *Health and Social Care in the Community* 15 (5), 426-438

World Health Organisation (2010) *Global recommendations on Physcial Activity for Health* [online] available from <http://apps.who.int/iris/bitstream/10665/44399/1/9789241599979_eng.pdf> [April 2013]

World Health Organisation (2002) *Innovative Care for Chronic Conditions: Building Blocks for Action.* 1st edn. Albany: World Health Organization

Wouters, E.F. (2003) 'Economic analysis of the Confronting COPD survey: an overview of results'. *Respiratory Medicine* 97 (Supplement C), S3-S14

Wright, C.C., Barlow, J.H., Turner, A.P., and Bancroft, G.V. (2003) 'Self-management training for people with chronic disease: An exploratory study'. *British Journal of Health Psychology* 8, 465-476

Yeo, J., Karimova, G., and Bansal S. (2005) 'Co-morbidity in older patients with COPD-its impact on health utilisation and quality of life, a community study'. *British Geriatrics Society* 35 (10), 33-37

Zigmond, A.S. and Snaith, R.P. (1983) 'The hospital anxiety and depression scale'. *Acta Psychiatrica Scandinavica* 67 (6), 361-370

Zwerink, M., van der Palen, J., van der Vaulk, P., Brusse-Keizer, M., and Effing, T. (2012) 'Relationship between daily physical activity and exercise capacity in patients with COPD'. *Respiratory Medicine* 107 (2), 242-248

Appendix 1: Literature Search Terms

Database Search:
EMBASE, MEDLINE, CINHAL, AHMED and Psychinfo

PICO Search Strategy

Population:
"pulmonary disease, chronic obstructive" OR COPD OR "chronic obstructive pulmonary disease"
[Limit to: Publication Year 1990-Current and English Language]

Intervention:
educat* OR self-manag* OR "self manag*" OR self-car* OR "self car*" OR train* OR instruct* OR "patient cent*" OR patient-cent* OR patientfocus* OR "patient focus*" OR patient-education OR "patient education" OR "management plan*" OR "management program*"
[Limit to: Publication Year 1990-Current and English Language]

Comparison:
"usual care" OR "GP care" OR rehabilitat* OR control
[Limit to: Publication Year 1990-Current and English Language]

Outcome:
exercise OR "health status" OR "quality of life" OR hospital* OR "healthcare utilisation" OR "healthcare utilization" OR knowledge OR activity
[Limit to: Publication Year 1990-Current and English Language]

Appendix 2: Editorial

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Appendix 3: Ethical Approval

NHS
National Research Ethics Service

Nottingham Research Ethics Committee 2
1 Standard Court
Park Row
Nottingham
NG1 6GN

Telephone: 0115 9123344 ext 68575
Facsimile: 0115 9123300

11th September 2007

Professor Sally Singh
Head of Pulmonary and Cardiac Reahbilitation
University Hospitals of Leicester
Glenfield Hospital
Groby Road
Leicester
LE3 9QP

Dear Professor Singh

Full title of study: **A self-management programme for Chronic Obstructive Pulmonary Disease (COPD): Is it effective in primary care - A pilot study**

REC reference number: **07/H0408/114**

Thank you for your letter of 07 September 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 20 August 2007. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form. Confirmation of approval for other sites listed in the application will be issued as soon as local assessors have confirmed they have no objection.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application		25 July 2007
Investigator CV		
Protocol	1	06 June 2007
Peer Review		24 July 2007
Interview Schedules/Topic Guides	1	06 June 2007
GP/Consultant Information Sheets	1	06 June 2007
Participant Information Sheet	1	06 June 2007
Participant Consent Form	2	04 September 2007
Response to Request for Further Information		07 September 2007
Letter of Invitation	1	06 June 2007
Self-Management Programme of Activity Coping and Education for COPD		
COPD Action Plan		

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from http://www.rdforum.nhs.uk/rdform.htm.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Feedback on the application process

Now that you have completed the application process you are invited to give your view of the service you received from the National Research Ethics Service. If you wish to make your views known please use the feedback form available on the NRES website at:

https://www.nresform.org.uk/AppForm/Modules/Feedback/EthicalReview.aspx

We value your views and comments and will use them to inform the operational process and further improve our service.

07/H0408/114:	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr M Hewitt/Ms L Ellis
Chair/Coordinator

Email: linda.ellis@nottinghamshirecounty-tpct.nhs.uk

Enclosures: Standard approval conditions

Site approval form

Copy to: R&D office for NHS care organisation at lead site - UHL

Appendix 4: Patient Information Sheet

University Hospitals of Leicester NHS
NHS Trust
Glenfield Hospital
Groby Road
Leicester
LE3 9QP

Tel: 0116 287 1471
Fax: 0116 258 3950
Minicom: 0116 287 9852

A self-management programme for chronic obstructive pulmonary disease (COPD): Is it effective in primary care?

(Version 4(04/10/2010)

You are being invited to take part in research study being conducted by Glenfield Hospital and Coventry University. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

1. What is the purpose of the study?

Over the last year we have developed a self-management manual for patients with Chronic Obstructive Pulmonary Disease (COPD). This has been done with enormous help from patients like yourself. We would now like to test the effectiveness of the manual.
The manual covers issues such as drug and symptom management, exercise and nutrition at home. This would give help and advice to manage COPD without travelling to the hospital.
This study is important in order to inform the current delivery of services to patient with COPD. We hope to optimise patient care and support the development of new COPD programmes of care.

2. Why have I been chosen?

As an individual with COPD you have been identified as a suitable participant. It is important to us to see how people in primary care progress using the manual we have developed in comparison to those who receive standard care from their GP. It will help us develop and improve future services with this knowledge.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

4. What will happen to me if I take part?

You will be able to take this patient information sheet home with you and you will be contacted by telephone to discuss participating in the study. If you agreed to take part in the research you will be placed at random into either the self-management or usual GP care group.

Once you have provisionally agreed to take part in the research you will be contacted to arrange a date and time to discuss the project in more detail. We don't know how effective the self management manual will be. To find out, we need to make comparisons between the different treatments. We put people into groups and give each group a different treatment; the results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The results are then compared. There will be a 50/50 chance of being allocated to either group.

Overall your involvement will last for 6 months, although the study will go on for much longer. For the purpose of this study we would ask you to attend the hospital on 3 occasions during which time we would measure your exercise capacity and ask you to fill in some questionnaires.
You may also be asked to take part in an interview at these visits. You do not have to complete an interview to be part of this research.

We would, with your permission, inform your General Practitioner that you have agreed to take part in this study

5. What do I have to do?

If you are assigned to the GP care group you will continue as normal with the treatment you receive from your GP. You will be requested to complete standard assessments of lung function, exercise capacity (walking test), a test to measure the strength of the muscles in your thigh and be asked to complete some questionnaires about your health status. You will be assessed at the beginning of the study, 6 weeks later and 6 months after. These assessments will take place at Glenfield Hospital or Coventry University and your travel expenses will be reimbursed.

If you are assigned to the self-management group you will undergo the same assessments at the same time points as the GP care group. This will be at Glenfield Hospital or Coventry University. However, you will also be given a manual for people with pulmonary disease and invited to a workshop at your GP surgery to have your self-management programme explained to you Your manual will outline how to manage your condition including information on drug and symptom management, exercise and nutrition. Included will be some home-based exercises you can carry out in your own time. You will

receive 2 phone calls to see how you are progressing with the manual during the first 6 weeks.

If you agree to take part in an interview, this will consist of an informal interview in which you will be asked some previously agreed questions relating to what you think about exercise and self-management. The interview shouldn't last longer than 1 hour and will be digitally recorded, with your permission.

You will also be invited to wear an activity monitor which is worn on your arm. This is to be worn for 7 consecutive days (please do not allow the monitor to get wet, so please remove if going swimming or you are having a bath etc.). You do not need to change your normal activity pattern while wearing this monitor. Again this will be assessed before you start your programme and also 6 weeks and 6 months after, as is routine.

6. What are the possible disadvantages and risks of taking part?

There are no foreseeable side-effects of taking part.

7. What are the possible benefits of taking part?

We hope that the research will aid you in your understanding of exercise and COPD and inform both present and future self-management programmes therefore benefiting COPD patients.

8. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangement. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

9. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you, which leaves the medical centre, will have your name and address removed so that you cannot be recognised from it. Participants will not be identified in any subsequent written material; for example, pseudonyms will be used to refer to participants' names. Results will be reported in such a way that completely preserves confidentiality.

10. What will happen to the results of the research study?

The results of the study will be disseminated in peer and lay journals, professional publications and presentations made at relevant conferences. Results will be reported in such a way that preserves confidentiality. All participants will also receive a summary of the results.

11. Who is organising and funding the research?

This study is being funded by Astra Zeneca and Research for Patient Benefit. You have been recruited through your GP surgery.

12. Who has reviewed the study?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by an NHS research Ethics Committee before it goes ahead. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information of which to make an informed decision.

13. Contact for further information

If you have any concerns or other questions about this study or the way it has been carried out, you should contact the principal researcher (Sally Singh Tel: 0116 2502535)

Contact for further information:
Katy Wagg
Self-management Programme
Pulmonary Rehabilitation
Glenfield Hospital,
Leicester,
LE3 9PQ

0116 2583652
katy.e.wagg@uhl-tr.nhs.uk

Thank you for reading this
Yours faithfully

Katy Wagg

Appendix 5: Consent Form

University Hospitals of Leicester NHS
NHS Trust
Glenfield Hospital
Groby Road
Leicester
LE3 9QP

Tel: 0116 287 1471
Fax: 0116 258 3950
Minicom: 0116 287 9852

CONSENT FORM (Version 5 (05/10/2010)

Identification Number for this study:

A self-management rehabilitation programme for chronic obstructive pulmonary disease (COPD) in primary care

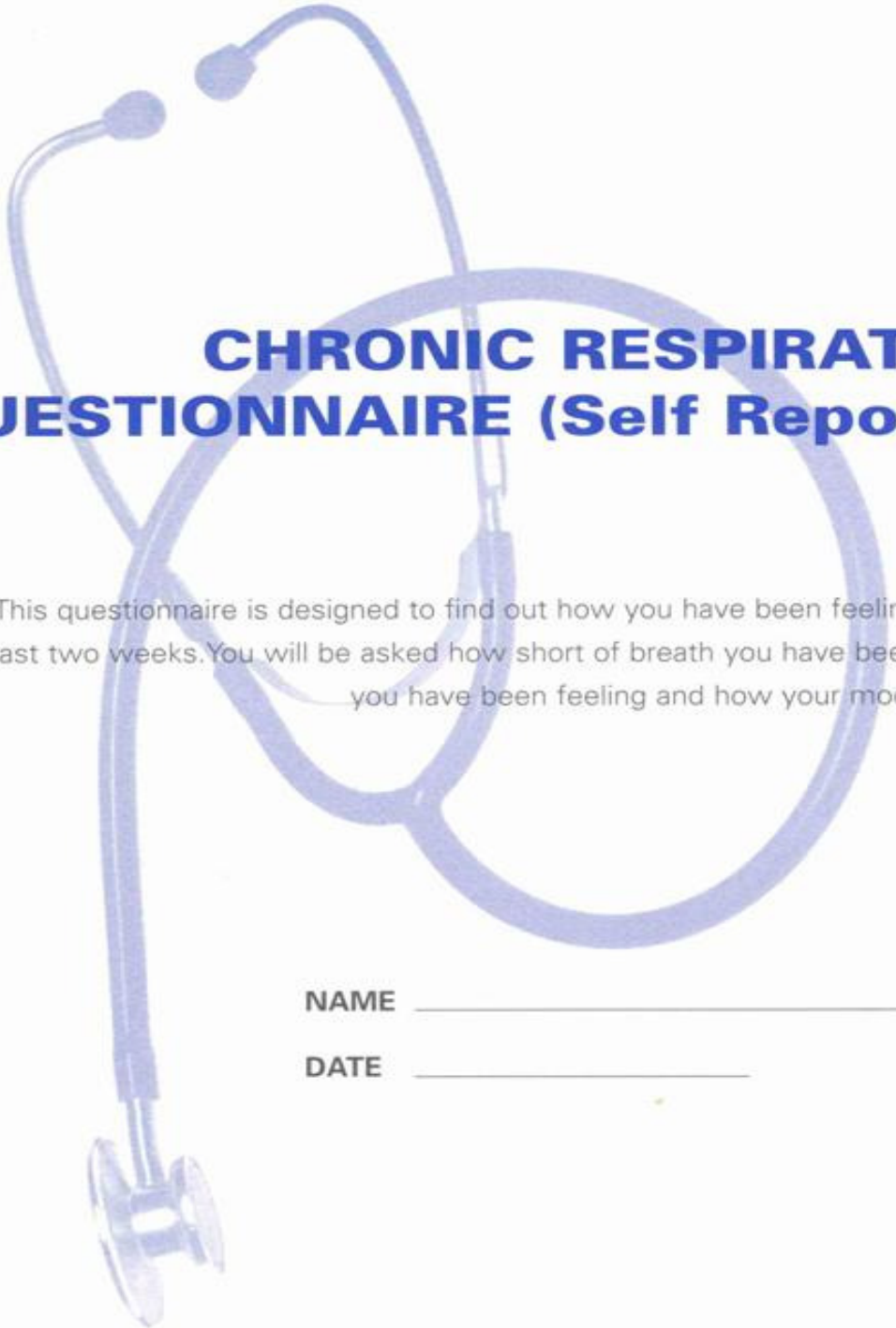
Please initial box

1. I confirm that I have read and understand the information sheet dated 04/10/2010 version 4 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Coventry University or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐
5. I agree for my GP to be informed of my participation. ☐
6. I agree to take part in taped interviews and for anonymous quotes to be used in the final report ☐
7. I understand that all the information I give will be treated in confidence. Should I disclose any information that highlights a breach of the law, or dangerous practice the interviewer will be duty bound to breach confidentiality. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Appendix 6: Chronic Respiratory Questionnaire – Self Report



CHRONIC RESPIRATORY QUESTIONNAIRE (Self Reported)

This questionnaire is designed to find out how you have been feeling during the last two weeks. You will be asked how short of breath you have been, how tired you have been feeling and how your mood has been.

NAME _____

DATE _____

University Hospitals of Leicester NHS
NHS Trust

(c) 2001. University Hospitals of Leicester NHS Trust, Glenfield Hospital, UK and McMaster University, Ontario, Canada (All rights reserved)

CHRONIC RESPIRATORY QUESTIONNAIRE (Self Reported)

We would like you to think of ways in which your shortness of breath limits your life. We are particularly interested in activities which you still do, but which are limited by your shortness of breath.

Listed below are some activities which can make people with lung problems feel short of breath.

If you have felt **short of breath** doing any of the **activities** listed below **during the last two weeks** then please tick each relevant activity. If you have **not** done the activity during the last two weeks or it does **not** make you short of breath then leave it blank.

THE ACTIVITIES ARE:

	1. BEING ANGRY OR UPSET
	2. HAVING A BATH OR SHOWER
	3. BENDING
	4. CARRYING - SUCH AS GROCERIES
	5. DRESSING
	6. EATING
	7. GOING FOR A WALK
	8. DOING YOUR HOUSEWORK
	9. HURRYING
	10. MAKING YOUR BED
	11. MOPPING OR SCRUBBING A FLOOR
	12. MOVING FURNITURE
	13. PLAYING WITH CHILDREN/GRANDCHILDREN
	14. PLAYING SPORTS
	15. REACHING OVER YOUR HEAD
	16. RUNNING - SUCH AS FOR A BUS
	17. SHOPPING
	18. WHILE TRYING TO SLEEP
	19. TALKING
	20. VACUUMING
	21. WALKING AROUND YOUR OWN HOME
	22. WALKING UPHILL
	23. WALKING UPSTAIRS
	24. WALKING WITH OTHERS ON LEVEL GROUND
	25. PREPARING MEALS

Please list **any other activities** that you have done during the last two weeks which have made you feel short of breath. These should be activities which you do frequently and which are important in your day-to-day life.

We would now like you to identify the **most <u>important</u> activities** in which you have been limited by your **shortness of breath** in the last **two weeks**.

Using the list you have made on the previous page, write down the **<u>five most important activities</u>** that have made you short of breath on the lines below. We would then like you to tell us **how short of breath** you have been while performing each activity by ticking the box which best describes how you feel.

HOW SHORT OF BREATH HAVE YOU BEEN DURING THE LAST TWO WEEKS WHILE PERFORMING THESE ACTIVITIES?

	Extremely short of breath	Very short of breath	Quite short of breath	Moderate shortness of breath	Some shortness of breath	A little shortness of breath	Not at all short of breath
1. _____	☐	☐	☐	☐	☐	☐	☐
2. _____	☐	☐	☐	☐	☐	☐	☐
3. _____	☐	☐	☐	☐	☐	☐	☐
4. _____	☐	☐	☐	☐	☐	☐	☐
5. _____	☐	☐	☐	☐	☐	☐	☐

PLEASE MAKE SURE YOU HAVE COMPLETED THE ABOVE TABLE BEFORE TURNING THE PAGE

Thank you

6. In general, how much of the time during the last 2 weeks have you felt frustrated or impatient?

Please indicate how often during the last 2 weeks you have felt frustrated or impatient by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

7. How often during the past 2 weeks did you have a feeling of fear or panic when you had difficulty getting your breath?

Please indicate how often you had a feeling of fear or panic when you had difficulty getting your breath by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

8. What about fatigue? How tired have you felt over the last 2 weeks?

Please indicate how tired you have felt over the last 2 weeks by ticking one of the following options from the list below.

1. EXTREMELY TIRED ❑
2. VERY TIRED ❑
3. QUITE A BIT OF TIREDNESS ❑
4. MODERATELY TIRED ❑
5. SOMEWHAT TIRED ❑
6. A LITTLE TIRED ❑
7. NOT AT ALL TIRED ❑

9. How often during the last 2 weeks have you felt embarrassed by your coughing or heavy breathing?

Please indicate how much of the time you felt embarrassed by your coughing or heavy breathing by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

10. In the last 2 weeks, how much of the time did you feel very confident and sure that you could deal with your illness?

Please indicate how much of the time you felt very confident and sure that you could deal with your illness by ticking one of the following options from the list below.

1. NONE OF THE TIME ❑
2. A LITTLE OF THE TIME ❑
3. SOME OF THE TIME ❑
4. A GOOD BIT OF THE TIME ❑
5. MOST OF THE TIME ❑
6. ALMOST ALL OF THE TIME ❑
7. ALL OF THE TIME ❑

11. How much energy have you had in the last 2 weeks?

Please indicate how much energy you have had by ticking one of the following options from the list below.

1. NO ENERGY AT ALL ❑
2. A LITTLE ENERGY ❑
3. SOME ENERGY ❑
4. MODERATELY ENERGETIC ❑
5. QUITE A BIT OF ENERGY ❑
6. VERY ENERGETIC ❑
7. FULL OF ENERGY ❑

12. In general, how much of the time did you feel upset, worried or depressed during the past 2 weeks?

Please indicate how much of the time you felt upset, worried or depressed during the past 2 weeks by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

13. How often during the last 2 weeks did you feel you had complete control of your breathing problems?

Please indicate how often you felt you had complete control of your breathing problems by ticking one of the following options from the list below.

1. NONE OF THE TIME ❑
2. A LITTLE OF THE TIME ❑
3. SOME OF THE TIME ❑
4. A GOOD BIT OF THE TIME ❑
5. MOST OF THE TIME ❑
6. ALMOST ALL OF THE TIME ❑
7. ALL OF THE TIME ❑

14. How much of the time during the last 2 weeks did you feel relaxed and free of tension?

Please indicate how much of the time you felt relaxed and free of tension by ticking one of the following options from the list below.

1. NONE OF THE TIME ❑
2. A LITTLE OF THE TIME ❑
3. SOME OF THE TIME ❑
4. A GOOD BIT OF THE TIME ❑
5. MOST OF THE TIME ❑
6. ALMOST ALL OF THE TIME ❑
7. ALL OF THE TIME ❑

15. How often during the last 2 weeks have you felt low in energy?

Please indicate how often during the last 2 weeks you have felt low in energy by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

16. In general, how often during the last 2 weeks have you felt discouraged or down in the dumps?

Please indicate how often during the last 2 weeks you felt discouraged or down in the dumps by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

17. How often during the last 2 weeks have you felt worn out or sluggish?

Please indicate how much of the time you felt worn out or sluggish by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

18. How happy, satisfied or pleased have you been with your personal life during the last 2 weeks?

Please indicate how happy, satisfied or pleased you have been by ticking one of the following options from the list below.

1. VERY DISSATISFIED, UNHAPPY MOST OF THE TIME ❑
2. GENERALLY DISSATISFIED, UNHAPPY ❑
3. SOMEWHAT DISSATISFIED, UNHAPPY ❑
4. GENERALLY SATISFIED, PLEASED ❑
5. HAPPY MOST OF THE TIME ❑
6. VERY HAPPY MOST OF THE TIME ❑
7. EXTREMELY HAPPY, COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED ❑

19. How often during the last 2 weeks did you feel upset or scared when you had difficulty getting your breath?

Please indicate how often during the past 2 weeks you felt upset or scared when you had difficulty getting your breath by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

20. In general how often during the last 2 weeks have you felt restless, tense or uptight?

Please indicate how often you have felt restless, tense or uptight by ticking one of the following options from the list below.

1. ALL OF THE TIME ❑
2. MOST OF THE TIME ❑
3. A GOOD BIT OF THE TIME ❑
4. SOME OF THE TIME ❑
5. A LITTLE OF THE TIME ❑
6. HARDLY ANY OF THE TIME ❑
7. NONE OF THE TIME ❑

Thank you very much for taking the time to complete this questionnaire.

Appendix 7: The Hospital Anxiety and Depression Scale

HOSPITAL ANXIETY and DEPRESSION SCALE (HADS)

Name: _____ **Date:** _____

e aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he able to help you more.

naire is designed to help your clinician to know how you feel. Read each item below and underline the reply closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the .

oo long over your replies, your immediate reaction to each item will probably be more accurate than a long esponse.

	A	D
I feel tense or 'wound up'		
Most of the time		**3**
A lot of the time		**2**
From time to time, occasionally		**1**
Not at all		**0**
I still enjoy 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 littIe, 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		
Not at all		
Worrying thoughts go through my mind		
A great deal of the time		
A lot of the time		
Not too often		
Very little		
I feel cheerful		
Never		
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 am slowed down		
Nearly all the time		**3**
Very often		**2**
Sometimes		**1**
Not at all		**0**
I get a sort of frightened feeling like 'butterflies' in the stomach		
Not at all	**0**	
Occasionally	**1**	
Quite often	**2**	
Very often	**3**	
I have lost interest in my appearance		
Definitely		**3**
I don't take as much care as I should		**2**
I may not take quite as much care		**1**
I take just as much care as ever		**0**
I feel restless as if I have to be on the move		
Very much indeed	**3**	
Quite a lot	**2**	
Not very much	**1**	
not at all	**0**	
I look forward with enjoyment to things		
As much a I ever did		**0**
Rather less than I used to		**1**
Definitely less than I used to		**2**
Hardly at all		**3**
I get sudden feelings of panic		
Very often indeed	**3**	
Quite often	**2**	
Not very often	**1**	
Not at all	**0**	
I can enjoy a good book or radio or television programme		
Often		**0**
Sometimes		**1**
Not often		**2**
Very seldom		**3**

Now check that you have answered all the questions

	A	D
TOTAL		

Appendix 8: Pulmonary Rehabilitation Adapted Index of Self-efficacy

General Self-Efficacy Scale.
Adapted for Pulmonary Rehabilitation.

Please circle where you feel you are now.

Statement	Score			
I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
If someone opposes me, I can find the means and ways to get what I want.	1	2	3	4
It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
I am confident that I can walk for a good distance, at my own pace, despite it making me breathless.	1	2	3	4
I am confident that I could deal efficiently with unexpected events.	1	2	3	4
Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
I feel confident that I will be able to perform the exercises asked of me during the course of rehabilitation, even if I find them difficult.	1	2	3	4
I can solve most problems if I invest the necessary effort.	1	2	3	4
I feel that I have an adequate amount of knowledge about my lung disease, despite it being a complex condition.	1	2	3	4
I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
I feel positive that I will be able to complete the exercises at home, despite there being no supervision from a health professional.	1	2	3	4
If I am in trouble, I can usually think of a solution.	1	2	3	4
I can handle whatever comes my way.	1	2	3	4
On a day to day basis I feel in control of my lung disease and how that affects my lifestyle, even when my symptoms become distressing.	1	2	3	4

Response Format.
1= Not at all true
2= Hardly true
3= Moderately true
4= Exactly true

Appendix 9: Bristol COPD Knowledge Questionnaire

NHS

BRISTOL COPD KNOWLEDGE QUESTIONNAIRE (BCKQ)©

Name: _____ **Date:** _____

This questionnaire is designed to find out what you know about your lung problem. It should be completed without help from anyone else. This usually takes between 10 and 20 minutes. Your answers will help us to find out what information you need to help you to understand and manage your lung condition.

Mark the circle which you think is the correct answer.

		True	False	Don't Know
1	**In COPD:**			
a	In COPD the word "chronic" means it is severe.	○	○	○
b	COPD can only be confirmed by breathing tests.	○	○	○
c	In COPD there is usually gradual worsening over time.	○	○	○
d	In COPD oxygen levels in the blood are always low.	○	○	○
e	COPD is unusual in people less than 40 years old.	○	○	○
2	**COPD:**			
a	More than 80% of COPD cases are caused by cigarette smoking.	○	○	○
b	COPD can be caused by occupational dust exposure.	○	○	○
c	Longstanding asthma can develop into COPD	○	○	○
d	COPD is commonly an inherited disease.	○	○	○
e	Women are less vulnerable to the effects of cigarette smoking than men.	○	○	○
3	**The following symptoms are *COMMON* in COPD:**	True	False	Don't Know
a	Swelling of ankles	○	○	○
b	Fatigue (tiredness)	○	○	○
c	Wheezing	○	○	○
d	Crushing chest pain	○	○	○
e	Rapid weight loss	○	○	○
4	**Breathlessness in COPD:**			
a	Severe breathlessness prevents travel by air.	○	○	○
b	Breathlessness can be worsened by eating large meals.	○	○	○
c	Breathlessness means that your oxygen levels are low.	○	○	○
d	Breathlessness is a normal response to exercise.	○	○	○
e	Breathlessness is primarily caused by a narrowing of the bronchial tubes.	○	○	○

5	Phlegm (sputum):	True	False	Don't Know
a	Coughing phlegm is a common symptom in COPD	○	○	○
b	Clearing phlegm is more difficult if you get dehydrated.	○	○	○
c	Bronchodilator inhalers can help clear phlegm.	○	○	○
d	Phlegm causes harm if swallowed.	○	○	○
e	Clearing phlegm can be assisted by breathing exercises.	○	○	○

6	Chest infections / exacerbations:	True	False	Don't Know
a	Chest infections often cause coughing of blood.	○	○	○
b	With chest infections phlegm usually becomes coloured (yellow or green).	○	○	○
c	Exacerbations (episodes of worsening) can occur in the absence of a chest infection.	○	○	○
d	Chest infections are always accompanied by a high temperature.	○	○	○
e	Steroid tablets should be taken whenever there is an exacerbation.	○	○	○

7	Exercise in COPD:	True	False	Don't Know
a	Walking is better exercise than breathing exercises to improve fitness.	○	○	○
b	Exercise should be avoided as it strains the lungs.	○	○	○
c	Exercise can help maintain your bone density.	○	○	○
d	Exercise helps relieve depression.	○	○	○
e	Exercise should be stopped if it makes you breathless.	○	○	○

8	Smoking:	True	False	Don't Know
a	Stopping smoking will reduce the risk of heart disease.	○	○	○
b	Stopping smoking will slow down further lung damage.	○	○	○
c	Stopping smoking is pointless as the damage is done.	○	○	○
d	Stopping smoking usually results in improved lung function.	○	○	○
e	Nicotine replacement therapy is only available on prescription.	○	○	○

9	Vaccination:	True	False	Don't Know
a	A flu jab is recommended every year.	○	○	○
b	You can get flu from having a flu jab.	○	○	○
c	You can only have a flu jab if you are 65 or over.	○	○	○
d	A pneumonia jab protects against all forms of pneumonia.	○	○	○
e	You can have a pneumonia jab and a flu jab on the same day.	○	○	○

10	Inhaled brochodilators:	True	False	Don't Know
a	All bronchodilators act quickly (within 10 minutes).	○	○	○
b	Both short and long acting bronchodilators can be taken on the same day.	○	○	○
c	Spacers (e.g. volumatic, nebuhaler, aerochamber) should be dried with a towel after washing.	○	○	○
d	Using a spacer device will increase the amount of drug deposited in the lungs.	○	○	○
e	Tremor may be a side effect of bronchodilators.	○	○	○

11	Antibiotic treatment in COPD:	True	False	Don't Know
a	To be effective, the course should last at least 10 days.	○	○	○
b	Excessive use of antibiotics can cause resistant bacteria (germs).	○	○	○
c	Antibiotics will clear all chest infections.	○	○	○
d	Antibiotic treatment is necessary for an exacerbation (worsening) however mild.	○	○	○
e	You should seek advice if antibiotics cause severe diarrhoea.	○	○	○

12	Steroid tablets given for COPD (eg Prednisolone):	True	False	Don't Know
a	Steroid tablets help strengthen muscles.	○	○	○
b	Steroid tablets should be avoided if there is a chest infection.	○	○	○
c	The risk of long-term side effects due to steroids is less with short courses than with continuous treatment.	○	○	○
d	Indigestion is a common side effect from using steroid tablets.	○	○	○
e	Steroid tablets can increase your appetite.	○	○	○

13	Inhaled steroids (brown, red or orange):	True	False	Don't Know
a	Inhaled steroids should be stopped if you are given steroid tablets.	○	○	○
b	Steroid inhalers can be used for rapid relief of breathlessness.	○	○	○
c	Spacer devices reduce the risk of getting thrush in the mouth.	○	○	○
d	Steroid inhaler should be taken before your bronchodilator.	○	○	○
e	Inhaled steroids improve lung function in COPD.	○	○	○

© Dr Roger White (roger.white4@virgin.net). All rights reserved. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means without the prior permission of the author.

Further supplies can be obtained from:
Department of Medicine (BCKQ)
Frenchay hospital,
Bristol BS16 1LE

Ref.: White R, Walker P, Roberts S, Kalisky S, White P, Chronic Respiratory Disease. 2006;3:123-131

Designed by the Medical Illustration Department, Frenchay Hospital, Bristol

Appendix 10: Contents page of SPACE FOR COPD manual

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Appendix 11: Aerobic training

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Appendix 12: Resistance Training

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Appendix 13: Action Plan

This item has been removed due to 3rd Party Copyright. The unabridged version of the thesis can be viewed in the Lanchester Library Coventry University.

Appendix 14: Telephone contact schedule

Telephone schedule

Date……..

1. How are you getting on with the manual?
2. What stage are you at currently? **1 2 3 4**
3. The walking programme: where are you now?
   a. **Frequency …… per day**
   b. **Time …… minutes in total**
   c. Provide encouragement to progress to next step
4. How many days a week do you use the manual? **…… average time**
5. How many A&E visits? **Respiratory…… Non-respiratory……**
6. How many hospital vists? **Respiratory…… Non-respiratory……**
7. How many visits to GP practice? **…….. regular check-ups**
   …….. practice nurse
   …….. GP
8. How many courses of: **…….. antibiotics**
   …….. steroids

Length of Call (mins):

Any questions?